UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA

SANDRA K. SHOEMAKER, Individually and On Behalf of All Others Similarly Situated,

Plaintiff,

v.

CARDIOVASCULAR SYSTEMS, INC. and LAURENCE L. BETTERLEY,

Defendants.

No. 0:16-cv-00568-DWF-TNL

Hon. Donovan W. Frank

Jury Trial Demanded

CLASS ACTION COMPLAINT

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Court-appointed Lead Plaintiffs, the City of Miami Fire Fighters' & Police Officers' Retirement Trust, the Norfolk County Retirement System, and the Wayne County Employees' Retirement System (collectively, "Lead Plaintiffs"), individually and on behalf of a class of similarly situated persons, by and through their undersigned counsel bring this securities class action on behalf of themselves and all persons and entities that, between September 12, 2011 and January 21, 2016, inclusive (the "Class Period"), purchased or otherwise acquired common stock of Cardiovascular Systems, Inc. ("CSI" or the "Company"), and were damaged thereby (the "Class"). Lead plaintiffs bring this class action to recover damages proximately caused to the Class by defendants' violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") against CSI and Laurence L. Betterley ("Betterley") (together, the "Defendants"). These allegations are based on Lead Plaintiffs' personal knowledge as to themselves and their own acts and on information and belief as to Defendants' acts and all other matters based upon all of the facts set forth below, which were obtained through investigations conducted by Co-Lead Counsel. Co-Lead Counsels' investigation on Lead Plaintiffs' behalf has included, among other things, a review of reports filed by CSI with the U.S. Securities and Exchange Commission ("SEC"); other regulatory reports filed by CSI; press releases and other public statements issued by CSI; securities analysts' reports concerning CSI; media and news reports concerning CSI; data and other information concerning CSI securities; publicly filed documents in litigation matters in which CSI is named as a defendant, including a qui tam action titled United States ex rel. Thams v. Cardiovascular Systems, Inc., No. 13-cv-00404 (W.D.N.C. July 15, 2013), Dkt. No. 1

(the "qui tam action")¹; other publicly available information concerning Defendants; interviews of former employees of CSI and other persons with knowledge of the matters alleged herein; and discussions with consulting experts. Lead Plaintiffs believe that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. NATURE OF THE ACTION

1. This securities class action arises from Defendants' false and misleading statements to investors concerning their purportedly scrupulous compliance with laws and regulations governing the marketing and sales of key medical devices, as well as the stability and growth prospects of the revenues derived from those same devices. Unbeknownst to investors, during the Class Period, Defendants were engaged in a widespread fraudulent scheme to artificially inflate sales revenues through a variety of illegal and illicit tactics, including off-label marketing and paying kickbacks to physicians, which were used to sell products that provided CSI with more than 88% of its revenues. When Defendants' statements were eventually revealed to be false in the wake of various corrective disclosures, including news of a Department of Justice investigation and a related *qui tam* lawsuit concerning CSI's illegal practices, the value of CSI's common stock plunged, wiping out nearly a billion dollars in market capitalization and causing substantial damages to Class members.

¹ The complaint in the *qui tam* action is attached hereto as **Exhibit A** and is expressly incorporated herein.

- 2. CSI is a medical technology company that develops, manufactures, and markets medical devices for the treatment of peripheral and coronary arterial diseases. Specifically, the Company sells catheters designed to eliminate calcified plaque that accumulates on vessel walls in the pelvis or leg. CSI employs this technology in its peripheral arterial disease ("PAD") devices. These products include: (i) the Stealth 360° Peripheral Orbital Atherectomy System ("OAS") and (ii) the Diamondback 360° Peripheral OAS (collectively, the "PAD Devices").
- 3. Throughout the Class Period, Defendants consistently represented to investors that CSI's sales and promotional practices regarding the PAD Devices, which generated year after year of double-digit growth in sales revenues, rigorously complied with legal and ethical standards. For example, Defendants repeatedly assured investors that "[b]ribery, kickbacks or other improper or illegal payments have no place in CSI's business;" that CSI "compli[ed] with all laws and regulations applicable to [its] business;" and that the Company "maintain[ed] rigorous policies and procedures to promote compliance with the False Claims Act and other regulatory requirements." CEO David L. Martin also frequently touted the growth of PAD sales during the Class Period, boasting of CSI's "double-digit growth;" highlighting CSI's plans "to accelerate and drive our next stage of growth in the PAD market;" and expressing bullish sentiments regarding CSI's "growth potential going forward." Thus, Defendants portrayed the Company's revenues from PAD Devices to be legal, stable and sustainable, with growth driven by superior technology, sales management, and clinical science.

- 4. In reality, the Company's sales and growth figures were the result of the systematic employment of illegal sales tactics. In particular, Defendants orchestrated a scheme wherein CSI paid illegal kickbacks to physicians, promoted the illegal, off-label use of products, coordinated quid-pro-quo referrals for top-purchasers of CSI products, and instructed physicians on methods to fraudulently bill for both off-label and unnecessary treatments. Thus, contrary to the picture of legal compliance and stable growth presented to investors, Defendants were engaged in a widespread fraudulent scheme to increase sales and inflate revenues. Indeed, based on the declines in revenues that the Company suffered in the wake of various partial corrective disclosures, sales attributable to illegal activities can be estimated to have amounted to approximately 15% of CSI's total revenues – if not much higher. Dependent as they were on illegal off-label uses and other improper sales tactics, CSI's sales of PAD Devices were in fact highly unstable, likely to lead to regulatory sanctions, a drop in sales and a consequent fall in CSI's stock price. To be sure, by the end of the Class Period, this is precisely what did happen, resulting in enormous losses for investors.
- 5. Consistent, first-hand accounts from over a dozen former CSI employees have confirmed that throughout the Class Period the Company's growing sales figures were in fact propelled by a sales force instructed and expected by senior management to meet the numbers "no matter what" and trained in various illegal marketing and sales tactics. For example, CSI's sales force engaged in and relied heavily on illegal kickbacks, impermissible off-label marketing, as well as the manufacturing of phantom sales to increase reported purchases of the Company's PAD devices. Indeed, the

Company's touted "double-digit" growth during the Class Period largely *depended* on its systematic violations of medical device marketing laws and regulations, as well as its and artificial inflation of sales numbers to boost the sales of the Company's products, and in turn, its share prices.

- 6. For example, CSI's PAD Devices are FDA approved and indicated for use with a catheter sized 6-French. Yet, multiple Confidential Witnesses ("CW"s) confirmed that CSI promoted the use of its PAD devices with a smaller catheter 4-French an illegal promotion of off-label use. Further, CSI's PAD Devices are indicated only to treat blood vessels below the waist; *i.e.*, in the legs and feet. Nevertheless, Defendants illegally promoted the off-label use of the Company's PAD Devices in areas above the waist such as in coronary lesions and coronary atherectomies.
- 7. Likewise, multiple CWs confirmed that CSI induced its sales force to use illegal kickbacks to boost sales of its medical devices. For example, among other things, CSI's sales force offered "free" products to induce the purchase of other products and engaged in "referral channel marketing" by which CSI would solicit and encourage third-party physicians to refer patients to physicians who would use CSI devices in return for these referrals. CSI also offered substantial financial assistance to help physicians open outpatient cardiac catheterization laboratories ("OBLs"). This illegal *quid pro quo* kickback strategy was intended to and did induce physicians to use and obtain reimbursement for use of CSI medical devices, artificially boosting sales of the devices and the Company's share prices.

- 8. These CW accounts of a widespread fraud at CSI to increase sales through illegal practices corroborate the similar allegations made in a recently unsealed *qui tam* complaint. This complaint was filed on July 15, 2013 by a former CSI sales manager pursuant to the *qui tam* provisions of the Federal False Claims Act, and alleged in detail how, over a period of at least five years, CSI instituted a Company-wide effort to maximize its profits through various illegal sales tactics and violations of U.S. Food and Drug Administration ("FDA") laws and regulations. Indeed, the *qui tam* complaint sets forth shocking factual allegations of CSI's "fraudulent marketing scheme to maximize its profits through an ongoing pattern of fraud and deception involving illegal kickbacks, off-label promotion and violations of FDA laws and regulations in connection with its medical devices used for the treatment of Peripheral Arterial Disease" including "CSI's Diamondback 360 device, Predator 360 device and Stealth 360 device."
- 9. CSI's fraudulent scheme was orchestrated by and directly involved executives at the very top of the Company, including CEO Martin and CFO Betterley. During the Class Period, these executives repeatedly touted the revenues and growth potential derived from sales of PAD Devices as well as the fact that they had hired and worked closely with the very CSI officials that multiple CWs identified as having heralded in the illegal practices at issue in this lawsuit. Thus, both Martin and Betterley knew of or had unfettered access to information about but recklessly disregarded the illegal sales tactics employed by CSI to drive up sales. Indeed, the fact that numerous CWs from locations across the United States corroborated the same illegal practices demonstrates that Defendants' fraudulent scheme was coordinated centrally by

CSI's very top executives, including Martin and Betterley. Moreover, during the Class Period, both CEO Martin and CFO Betterley engaged in a highly suspicious pattern of insider trading – as they collectively sold over 800,000 shares worth of their personal holdings in CSI common stock, generating more than \$21 million in illicit proceeds. Underscoring the suspicious nature of their trading, Martin and Betterley's Class Period sales of CSI stock, represented a 700% increase over the CSI common stock that they had sold for the prior two-year period, and in turn generated profits of more than 1,800%, over the prior period.

- 10. The truth concerning Defendants' fraudulent scheme began to leak out on May 9, 2014, when the Company announced that it had received notice that the United States Attorney's Office for the Western District of North Carolina (the "Department of Justice" or "DOJ") was investigating the Company "to determine whether the Company has violated the False Claims Act, resulting in the submission of false claims to federal and state health care programs, including Medicare and Medicaid." On this news, the price of CSI shares declined \$2.51 per share, or more than 8%, from an open of \$29.94 per share on May 12, 2014, to close at \$27.43 per share that day.
- 11. Realizing that it could no longer orchestrate illegal sales tactics with impunity in the wake of the DOJ investigation and the related unsealing of the *qui tam* complaint, the Company began to reform its illegal practices and expand its sales force. This strategy was designed to both make up for and hide the loss of CSI's sales resulting from illegal business practices. However, CSI's efforts to mask the revenue

declines resulting from the drop-off in illegal activity failed as the Company announced quarter after quarter of disappointing financial results.

- 12. On October 7, 2015, as part of its financial results for the first quarter of fiscal year 2016, CSI revealed staggering losses due to its abandonment of its illegal sales and marketing practices. The Company's revenue fell over 9% from \$48.5 million the prior quarter to \$43.9 million. These losses were compounded the following quarter when, on January 21, 2016, CSI announced that its revenues had fallen by an additional \$2.5 million. Thus, in merely two quarters, the Company's revenues fell by nearly 15% and the market realized that CSI's revenue stream had been irrevocably damaged by the DOJ investigation and resulting "chill" on illegal activity. Subsequently, in early 2016, reports surfaced that the Company was then engaged in the process of settling the *qui tam* suit for approximately \$8 million.
- 13. As set forth herein, Defendants' materially incomplete, false, and misleading Class Period statements concerning the sales figures for its core products, as well as the way in which those sales were achieved, artificially inflated investors' confidence in the Company as well as the price of the Company's common stock. As revelations of Defendants' prolific illegal sales tactics came to light causing Defendants to cease those illegal activities with a resulting decline in revenues the Company's common stock experienced severe and statistically significant declines. Indeed, the price of the Company's shares plunged from a Class Period high of \$40.98 per share on April 9, 2015, to \$8.74 per share at markets' close on January 22, 2016, the day after the Class

Period, a decline of nearly 80% and a market capitalization decline of nearly one billion dollars. This lawsuit seeks to recover for the substantial losses suffered by investors.

II. JURISDICTION AND VENUE

- 14. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b), and 78t(a), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5.
- 15. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, and Section 27 of the Exchange Act, 12 U.S.C. § 78aa.
- 16. Venue is proper in this District pursuant to Section 27 of the Exchange Act, 15 U.S.C. §78aa, and pursuant to 28 U.S.C. § 1391(b) because CSI's principal executive offices are located within this District and many of the acts and transactions alleged herein, including the preparation and dissemination of materially false and misleading information, occurred in substantial part in this District.

III. PARTIES

A. Lead Plaintiffs

17. Lead Plaintiff Norfolk County Retirement System ("Norfolk County") is a pension plan headquartered in Canton, Massachusetts, providing retirement benefits for the public employees of Norfolk County. As set forth in the certification previously filed with the Court, Norfolk County purchased shares of CSI common stock during the Class Period and suffered damages as a result of the federal securities law violations alleged herein. By Order dated April 26, 2016, the Court appointed Norfolk County as a Lead Plaintiff in this action.

- 18. Lead Plaintiff Wayne County Employees' Retirement System ("Wayne County") is a pension plan headquartered in Detroit, Michigan, providing retirement benefits for the public employees of Wayne County. As set forth in the certification previously filed with the Court, Wayne County purchased shares of CSI common stock during the Class Period and suffered damages as a result of the federal securities law violations alleged herein. By Order dated April 26, 2016, the Court appointed Wayne County as a Lead Plaintiff in this action.
- 19. Lead Plaintiff City of Miami Fire Fighters' & Police Officers' Retirement Trust ("Miami FIPO") is a pension plan headquartered in Miami, Florida, providing retirement benefits for the fire fighters and police officers of the City of Miami. As set forth in the certification previously filed with the Court, Miami FIPO purchased shares of CSI common stock during the Class Period and suffered damages as a result of the federal securities law violations alleged herein. By Order dated April 26, 2016, the Court appointed Miami FIPO as a Lead Plaintiff in this action.

B. Defendants

20. Defendant CSI develops and manufactures medical devices for the treatment of peripheral and coronary arterial diseases. CSI is a Delaware corporation with its principal executive offices located at 1225 Old Highway 8 Northwest, St. Paul, Minnesota 55112. CSI went public on February 25, 2009, after a reverse merger with Replidyne Inc. During the Class Period, CSI common stock, at all times relevant here, traded under the ticker symbol "CSII" on the NASDAQ Stock Market LLC ("NASDAQ"), which is an efficient market.

- 21. CSI's fiscal year ends on June 30 of each year and CSI's fiscal Q1, Q2, Q3, and Q4 ends on September 30, December 31, March 31, and June 30, respectively.
- 22. Defendant Betterley has been the Company's Chief Financial Officer ("CFO") and an Executive Officer since April 2008. Prior to joining CSI, Betterley was Chief Financial Officer at Cima NanoTech, Inc. from May 2007 to April 2008, Senior Vice President and Chief Financial Officer of PLATO Learning, Inc. from 2004 to 2007, Senior Vice President and Chief Financial Officer of Diametrics Medical, Inc. from 1996 to 2003, and Chief Financial Officer of Cray Research Inc. from 1994 to 1996. Betterley was a direct and substantial participant in the fraud. During the Class Period, as more fully alleged below, Betterley made materially incomplete, false and misleading statements. Betterley and CSI are referred to together as "Defendants."

IV. RELEVANT NON-PARTY

23. David L. Martin ("Martin"), recently deceased, was the Company's President and Chief Executive Officer ("CEO") throughout the Class Period. Martin had been CSI's President and CEO since February 2007 and a member of the Board of Directors since August 2006. Martin also served as CSI's Interim CFO from January 2008 to April 2009. Prior to joining CSI, Martin was Chief Operating Officer of FoxHollow Technologies, Inc. from January 2004 to February 2006, Executive Vice President of Sales and Marketing of FoxHollow Technologies, Inc. from January 2003 to January 2004, Vice President of Global Sales and International Operations at CardioVention Inc. from October 2001 to May 2002, Vice President of Global Sales for RITA Medical Systems, Inc. from March 2000 to October 2001 and Director of U.S.

Sales, Cardiac Surgery for Guidant Corporation from September 1999 to March 2000.

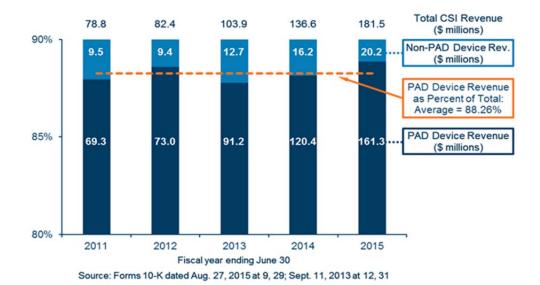
Mr. Martin has also held sales and sales management positions for The Procter & Gamble Company and Boston Scientific Corporation. Martin was a direct and substantial participant in the fraud. During the Class Period, as more fully alleged below, Martin made materially incomplete, false and misleading statements. Martin died on May 1, 2016.

V. <u>FACTUAL ALLEGATIONS</u>

A. Overview Of The Company And Its Business

- 24. CSI is a manufacturer of medical devices, self-described in its SEC filings as "leading the way" in treatments for peripheral and coronary arterial diseases. The Company's PAD Systems, its most important line of products, help physicians treat the build-up of arterial plaque composed of excess calcium. CSI's PAD Devices are FDA-approved to remove this calcium buildup along the walls of target blood-vessels by using an orbital spin to break the buildup down into particles smaller than blood cells.²
- 25. Throughout the Class Period, CSI candidly acknowledged the singular importance of PAD Device sales to the Company's business and future prospects, as the Company derived "substantially all of [its] revenue from the sale of PAD Systems." Indeed, during the Class Period, CSI's sales of PAD Devices amounted to an average of 88.26% of its total revenues:

The standard alternative FDA-recognized procedure is a balloon angioplasty, a procedure in which a catheter is used to reach the blockage in the artery and a balloon attached to the catheter is inflated to flatten the blockage. A balloon angioplasty has a substantially longer record of safe and effective use, and costs substantially less, than procedures performed using CSI's PAD Devices.



26. On each quarterly earnings call with analysts and other market participants during the Class Period, CSI touted the amount of its medical device sales for that quarter and confirmed the percentage of total revenues derived from the sale of its PAD Devices. According to Defendants, sales from PAD Devices were the main driver of the Company's explosive revenue growth in each year from 2011 to 2015:

Fiscal Year Ending	Revenues for Device Sales (in millions)	Total CSI Revenue (in millions	Percentage
June 30, 2011	\$69.3	\$78.8	88%
June 30, 2012	\$73.0	\$82.5	88%
June 30, 2013	\$91.2	\$103.9	88%
June 30, 2014	\$120.4	\$136.6	88%
June 30, 2015	\$161.3	\$181.5	89%

Source: SEC Form 10-K, dated August 27, 2015, at 9, 29. Source: SEC Form 10-K, dated September 11, 2013, at 12, 31

27. Buoyed by these strong purported revenue numbers, analysts viewed CSI as a growth company driven by strong sales of its PAD products. For example, Feltl and Company issued a report on May 3, 2012 describing CSI as a "rapidly growing medical

device company." Leerink Swann analysts issued a report on April 18, 2013, praising CSI for "its long-term sales growth profile in the top-tier of the comparable group." Benchmark issued a report on March 15, 2013 similarly stating that "[w]e believe that CSII has one of the best revenue growth profiles in the medical device sector."

28. Throughout the class period, CSI touted its own growth as well. On an earnings call on October 6, 2011, shortly after the start of the Class Period, CEO Martin predicted that CSI "will have double-digit growth at year-end." A year later, on the October 30, 2012 earnings call, Martin detailed CSI's plans "to accelerate and drive our next stage of growth in the PAD market." Even after the qui tam complaint had been filed, CSI continued to express bullish growth expectations, and on the August 7, 2013 earnings call, Martin again assured investors that "[w]e feel confident about our growth potential going forward."

B. Sales And Marketing Of CSI's PAD Devices Are Strictly Regulated

29. As far as investors were aware, CSI had legitimate reasons to project strong growth, as its strong sales figures for its core products were achieved in an industry governed by regulations that, among other things, strictly prohibit the payment of kickbacks and off-label promotion to medical professionals to drive sales. Thus, to assure investors of its PAD Device sales stability and robust growth potential, CSI specifically touted its scrupulous legal and regulatory compliance. Indeed, during the Class Period, Defendants repeatedly represented to investors that "[b]ribery, kickbacks or other improper or illegal payments have no place in CSI's business;" that CSI "compli[ed] with all laws and regulations applicable to [its] business;" and that the

Company "maintain[ed] rigorous policies and procedures to promote compliance with the False Claims Act and other regulatory requirements."

- 30. The legal regime governing CSI's business was strict, but reasonably straightforward. The federal Anti-Kickback Statute prohibits healthcare providers from receiving remuneration paid with the intent to induce orders, including *quid pro quo* referrals of patients in exchange for prescription of treatments. Such remunerations, paid to induce or reward physicians' prescriptions or use of a company's products, constitute kickbacks that lead to increases in expenses for government-funded health benefit programs by incentivizing medically unnecessary treatments and excessive reimbursements. Kickbacks also unfairly reduce a patient's healthcare choices, as physicians may prescribe treatments based on the physician's own financial interests rather than according to the patient's medical needs.
- 31. The Company's sales and marketing of its products were also tightly regulated with respect to the approved uses—and therefore the approved-for-marketing uses—of its devices. The Federal Food, Drug, and Cosmetic Act ("FDCA") and the Food and Drug Administration's ("FDA") regulations govern, among other things, the advertising and promotion as well as sales and distribution of medical devices. Under the FDCA, no medical device may be marketed in the U.S. without FDA approval.
- 32. To market a product, companies typically must obtain FDA marketing authorizations known as the premarket application approval, or "PMA approval," a costly and time-consuming process when the product is new and previously approved. Once a medical device is cleared or approved by the FDA, the applicant may sell and market the

device to the public, but *only for the FDA-approved use*, which must appear on the product's labeling. 21 U.S.C. § 352(f); 21 C.F.R. § 801.5. If the manufacturer intends the product to be used for a new indication, the manufacturer must obtain FDA authorization for the new use. 21 C.F.R. § 807.81(a)(3); 21 C.F.R. § 801.4.

- 33. If off-label uses are included in the product's labeling, the product is "adulterated," and if off-label uses are promoted, the product is "misbranded." 21 U.S.C. §§ 351(f)(1)(B), 352(f). Manufacturing or introducing an adulterated or misbranded product into interstate commerce is strictly prohibited. 21 U.S.C. § 331(a-c), (g). Thus, the FDCA and the corresponding FDA regulations prohibit manufacturers from promoting a medical device for off-label uses. Simply put, the promotion of off-label uses of a medical device by a manufacturer is highly illegal. But this is exactly what Defendants did during the Class Period.
- 34. In August 2007, the FDA granted CSI clearance for the use of the Diamondback 360° as a therapy in patients with PAD through the 510(k) process. CSI was granted 510(k) clearance for the Stealth 360° in March 2011 and the Diamondback 360° 60cm Peripheral OAS in March 2014. Crucially, the FDA did *not* clear these PAD Devices for use in coronary arteries, bypass grafts, stems, or where thrombus or dissections are present. Use of CSI's PAD Devices in these manners was therefore considered off-label, and any promotion, marketing or encouragement of these devices for such off-label uses was illegal. As set forth below, promoting off-label use of PAD Devices was exactly what Defendants did right up until the DOJ investigation was announced.

- C. <u>Undisclosed To Investors, Defendants Trained And Encouraged</u>
 Representatives To Aggressively Promote Off-Label Use Of Its Devices
- 35. Throughout the Class Period, Defendants knowingly or recklessly used illegal, unsustainable, and undisclosed sales tactics to boost sales of the Company's PAD Devices. The purpose and effect of CSI's illegal sales tactics was to increase sales of its devices, creating the false impression that the sales of the PAD Devices, and by extension, the Company's overall financial prospects, were growing and sustainable.
- 36. As confirmed by over a dozen former employees with detailed knowledge of CSI's Class Period sales tactics, CSI induced its sales force to use illegal kickbacks and off-label promotion to sell PAD Devices and trained its sales force to instruct physicians in how to seek improper and fraudulent reimbursement of PAD Devices.

 These former employees each worked for CSI in different regions across the United States, demonstrating that the practices they described were widespread throughout the Company and, therefore, inevitably the product of coordination from the very top executives of CSI, including Defendant Betterley and now-deceased CEO, David Martin. As the former employees have provided information in confidence, these confidential witnesses will be identified herein by number (e.g. CW1, CW2, etc.).
 - 1. <u>CSI Trained and Encouraged Off-Label Marketing Of Its PAD</u>

 <u>Devices For A Smaller Unapproved Catheter</u>
- 37. Throughout the Class Period, a key component of CSI's plan to artificially inflate sales was the encouragement of physicians to use its PAD Devices in vessels that did not appear to contain calcium blockages or plaque. This practice constituted illegal, off-label marketing by CSI.

- 38. In furtherance of Defendants' decision to market the off-label use of the Company's medical devices, during the Class Period, Defendants authorized employees of the Company to: (a) develop sales and promotional strategies for field sales personnel designed specifically to convince doctors to use CSI's PAD Devices for off-label uses; and (b) distribute training and promotional materials promoting off-label use. These actions were illegal.
- 39. CSI's PAD Devices use catheters, one end of which is attached to the device, with the other inserted into the body in order to house and transport the spinning end of the device to the blood vessel to be treated. The French Catheter Scale is a common sizing convention for catheters: the smaller the number, the smaller the dimension of the catheter tube.
- 40. CSI's PAD Devices are FDA approved and indicated for use with a catheter sized 6-French. A 6-French catheter measures 2 mm in diameter, because of its relatively larger size, it cannot fit in many smaller blood vessels. Smaller blood vessels, like those that might be found in the foot ("pedal vessels") or calf ("tibial vessels"), would need to be accessed using a smaller-sized catheter, such as a 4-French catheter.
- 41. As Defendants knew, this sizing restriction limited the areas of the body in which physicians could use its PAD Devices. However, instead of demonstrating safety and efficacy with a smaller catheter and gaining FDA approval, CSI decided to market its devices off-label for use with the smaller size 4-French catheters. This off-label marketing is prohibited by FDA regulations.

- 42. As set forth in the *qui tam* action, CSI Regional Sales Manager Frank

 Natale told his sales representatives, "Our Value Story includes, [a]lthough off label,

 1.25 and 1.5 crowns can fit through a SF system. 1.25 micros can go 4F[rench]

 pedal/tibial access." *Qui tam* action ¶ 95. More than merely trumpeting the possibilities,
 the *qui tam* action also alleged that at CSI's medical education trainings, CSI simply
 taught physicians outright to operate its PAD Devices using a 4-French catheter. *Qui tam*action ¶ 97.
- 43. CW2, employed at the Company from 2012 until 2014 as a Sales Specialist in Florida, corroborated the qui tam allegations, explaining that CSI encouraged the offlabel promotion of its products with a smaller catheter, stating that although the Stealth 360 was approved for use limited to the 6-French catheter, CSI sales specialists specifically encouraged the use of the smaller, 5, or 4-French catheter with that device. CW2 recalled that trainings were held where both sales reps and doctors were specifically trained with 5-French and 4-French catheters, which were not approved uses. Sales reps were then told to suggest to doctors who were uncertain to use the smaller catheter sizes. Indeed, CW2 emphasized that the catheter-sizing the Company encouraged was almost always off-label, and stated that CSI even produced a document to give to physicians, showing them how much money it would save them to use the unapproved 5-French instead of the approved 6-French catheter. Similar practices were encouraged through the intentional hiring of inexperienced sales personnel with no clinical knowledge or background whatsoever, who simply told customers to use the device, or "spin it," no

matter what the indication was, with managers specifically approving sales reps to tell doctors that it was okay to use CSI's devices in un-approved areas.

- 44. CW5, a Field Clinical Specialist who worked at CSI from 2014-2015, further corroborated allegations of off-label marketing by sales reps, and stated that CSI's sales representatives encouraged physicians to use CSI's PAD Devices in every single case whether indicated for it or not. In fact, since CW5 was not a part of the sales force, and only worked at customers' offices for research purposes, sales reps would request that CW5 not point out that CSI devices were being used contrary to the indications for which they were labeled.
- 45. By marketing its PAD Devices as appropriate to use off-label with the smaller 5 and 4-French catheters, CSI was able to greatly expand the universe of blood vessels in which physicians used its PAD Devices. This allowed CSI to increase its PAD Devices sales (and revenues) while leaving investors unaware that those sales relied on illegal off-label marketing that was prohibited by the FDA.
 - 2. <u>CSI Promoted Off-Label Use Of Its Devices In Unapproved Areas Of The Body And Non-existent Disease States</u>
- 46. CSI's PAD Devices are indicated only to treat blood vessels below the waist; *i.e.*, in the legs and feet. CSI violated the law by ignoring this limited indication and instead marketing its products for far broader uses. For example, CSI actively promoted its PAD Devices for use in coronary lesions and coronary atherectomies. Coronary arteries and veins are those vessels that connect directly to the heart and are located in the chest. Though it understood that such use was off-label, CSI promoted

spinning its PAD Devices in coronaries even if there was no evidence of obstructions based on the theory that spinning causes no harm and there might be undetectable calcium in those vessels.

- 47. More than simply promoting such off-label and unnecessary use, CSI went so far as to show physicians and their staff how to bill and gain reimbursement from government funded healthcare programs for such procedures and even which procedure codes to use for such billing. Procedure codes, more colloquially known as Medical Billing Codes, is a system of classification in use by Medicare and Medicaid since the 1980s to identify treatments for reimbursement purposes. In order to obtain a reimbursement, providers must submit the correct procedure code on their reimbursement forms to government healthcare agencies.
- 48. Remarkably, CSI prominently displayed procedure codes for unapproved uses of its devices on its website. As the below screenshot of CSI's website shows, the Company promoted off-label use of its products by advertising to physicians how to code for procedures on coronaries, actively exhorting physicians to "share these codes with your hospital coder" even while admitting that it "does not have a device that is currently indicated for coronary use."

Procedure Coding

These codes will help track severely calcified coronary lesions and coronary atherectomy*:

Procedure Code (NEW):

 17.55 Transluminal Coronary Atherectomy, Directional Atherectomy, Excimer Laser Atherectomy, Rotational Atherectomy, that by laser, that by percutaneous approach, that by transluminal extraction

Diagnosis Code (NEW):

 414.4 Coronary Atherosclerosis due to calcified coronary lesion; coronary atherosclerosis due to severely calcified coronary tesion, code first coronary atherosclerosis (414.00-414.07)

Inpatient Hospital Procedure Code (REVISED):

O 00.66 is modified to describe PTCA only instead of PTCA or coronary atherectomy

Help track the cost of calcification:

- 1. Share these codes with your hospital coder
- 2. Encourage documentation of "severely calcified lesions" and "atherectomy" in patient records

*Cardiovascular Systems, Inc. does not have a device that is currently indicated for coronary use.

Qui tam action ¶ 103

- 49. The page displaying these codes was later deleted from CSI's website, but a cursory search of CSI's revamped website shows a November 28, 2011 Press Release entitled "New Reimbursement Codes Introduced to Better Track Costs of Treating Patients with Severely Calcified Lesions." The article begins with the bolded words, "Cardiovascular Systems led the effort to establish new codes," and goes on to lay out the myriad ills of untreated coronary calcium plaque, before prominently displaying the same procedure codes above again.³
- 50. Thus, not only did CSI display the procedure codes on its website and delete them after their appearance in a law suit, the Company in fact *procured* their introduction into the medical billing system that government funded healthcare programs relied on to issue reimbursements. At the very end of the news release, CSI noted that it

³ The Press Release is attached hereto as **Exhibit B**.

was then undertaking clinical trials for its coronary product, but it was not until October, 2013, nearly two years later, that the FDA granted PMA approval for the Company's coronary device. It begs the question why a company that was still in the midst of clinical trials, and nowhere near to obtaining FDA approval for a product, would "lead the way" in securing Medicaid and Medicare billing codes for procedures that they were years away from being able to legally market to physicians.

- 51. Furthermore, according to the *qui tam* action, CSI also promoted its PAD Devices through a "Cost of Calcium" presentation, specifically aimed at increasing the off-label use of CSI's PAD Devices. *Qui tam* action ¶ 62. Ostensibly, the PAD Devices would remove potentially dangerous calcium from blood vessels, but the Cost of Calcium presentations made clear that physicians should use the PAD Devices even when there was no evidence of calcium in the vessels. CSI encouraged this use and assured physicians that even if there was no calcium in the vessels, they would not do any harm by performing the procedure with the PAD Devices. That is, CSI actively encouraged use of its PAD Devices in patients who had no evidence of calcium in their vessels and for whom treatment was not medically necessary. *Qui tam* action ¶ 63.
- 52. CSI knew the impact of the Cost of Calcium presentations. As set forth in the *qui tam* action, CSI Area Sales Director Jason Fore wrote: "Without a doubt, this is the single most important message we have right now . . ." *Qui tam* action ¶ 67.
- 53. CSI also used off label promotion to tout its PAD Devices for use in treating Chronic Total Occlusions ("CTOs"), which are complete blockages of an artery. CTOs are a serious condition and most physicians prefer to perform a bypass on such

vessels, which has the best long-term data supporting its effectiveness. However, as set forth in the *qui tam* action, because CSI has a promotional agreement with Asahi Intecc for use of their Periphery Guide Wires, CSI encouraged physicians to use the unapproved Asahi guide wires and to "Force" their way through the occlusion or blockage. *Qui tam* action ¶¶ 106-110.

54. Finally, as also confirmed in the *qui tam* action, CSI Regional Sales Manager Natale told his sales representatives to market CSI's PAD Devices as the "[m]ost deliverable atherectomy device commercially available—Micro Crown gets us EVERYWHERE....Brachial Access/Femoral Access/Pedal/Tibial Access/Retrograde/Antegrade—We can do it all." *Qui tam* action ¶ 111.

D. <u>Unbeknownst To Investors, CSI Engaged In An Illegal Kickback</u> Program To Boost Sales Of Its Medical Devices

55. According to multiple confidential witnesses, whose statements corroborate allegations outlined in the *qui tam* complaint, CSI induced its sales force to use illegal kickbacks to boost sales of its medical devices including: (1) "free" products to induce the purchase of other products; (2) so-called referral channel marketing, through which CSI would solicit and encourage third-party physicians to refer patients to physicians who would use CSI devices in return for these referrals; and (3) substantial financial assistance to help physicians open outpatient cardiac catheterization laboratories ("OBLs"). CSI's illegal *quid pro quo* kickback strategy was intended to and did induce physicians to use and obtain reimbursement for use of CSI medical devices, artificially boosting sales of the devices and the Company's share prices.

- 1. <u>CSI Provides Physicians With Free Products—Billed To The</u>
 <u>Government—To Induce The Purchase Of Other Products</u>
- 56. CSI offered valuable consideration to physicians in the form of "free" CSI products—that were later billed to government payors—when physicians purchased other CSI products. As confirmed in the *qui tam* complaint, CSI Regional Sales Manager John Wilhelmy instructed his sales representatives to "find a way to drop in 6 Stealth and offer 1 for free!!!" He further encouraged sales representatives to "d[o] the math for your customer [to] show a significant % and \$ saving" and to "ensure that you do not leave any money on the table!!!" *Qui tam* action at ¶¶ 70, 72. Several confidential witnesses verified these allegations, and confirmed that CSI consistently offered a buy-6-get-1-free deal to physicians purchasing its PAD Devices. At contract prices of over \$3000, each buy-6-get-1-free deal therefore represented a kickback worth thousands of dollars. These "free" products were typically offered at the end of each quarter to ensure CSI sales exceeded investors' expectations.
- 57. According to CW1, who was employed by the Company from 2010 until 2012 as a District Sales Manager in New York, CSI provided doctors with free products in 'buy some get some free' deals. However, because the Company did not want the fact that it was giving such deals to appear on its books, which would lower the product's average sales price, these free items were given away outright and described as "products [that fell] off of the truck."
- 58. CW2 further corroborated the allegations in the *qui tam* action, stating that the giving of kickbacks to healthcare providers "absolutely occurred," and that Medicare

fraud was rampant throughout the Company. Consistent with the allegations in the *qui* tam action, CW2 explained that not only did CSI give away free products to physicians, but Company management sent out emails throughout the quarter specifically instructing sales representatives to offer healthcare providers free products in the form of buy 6-get-1 or buy 3-get-1 free deals. Regional Sales Manager Darcy Terrell, as well as Terrell's superior, Area Sales manager Aaron Lew, personally gave such instructions to offer free products to CW2, who stated that these free products were then billed by the recipient healthcare providers to government payors, such as Medicare and Medicaid.

- 59. CW2 also attended quarterly sales meetings where the managers gave PowerPoint presentations highlighting the various deals and free products that the sales specialists were told to offer physicians and practice groups. CW2 stated that these meetings were held two weeks before each quarter end and that Senior Vice President of Sales Jim Breidenstein ("Breidenstein") attended CW2's last team meeting in Florida where the free product offers were discussed. CW2 also reported that the deals got better as the quarter progressed, and offers such as buy 3-get-1 free became common at quarter end.
- directly to the CEO during his tenure, and rose to the position of Vice President in the Company. CW3 also heard about the existence of illegal sales practices during and after his time at the Company. CW3 stated that while CSI began as a compliant and ethical business, it began to seek other ways to raise revenues as sales plateaued in the beginning of 2012. Specifically, CW3 reported that the Company responded to slowing sales by

bringing in a new VP of sales, Jim Breidenstein, who implemented a number of unscrupulous sales practices across the sales force. Among other tactics, Breidenstein pressured sales reps to operate with the understanding that, if doctors came to a training, they should be made to commit to purchasing a certain number of devices. CW3 also heard of instances where sales reps purchased gifts, which they would parlay into more sales. Sales rose dramatically in the wake of Breidenstein and Executive Vice President of Sales & Marketing, Kevin Kenny's, entry into the Company, and CW3 commented that it could not have been a coincidence that sales numbers exploded, and that CW3 did not understand how the two could have obtained the sales they did given that it had become so difficult to grow sales by legitimate means.

- 61. CW4, who worked at the Company from 2008 until 2012, and who served for two years as a District Sales Manager in the Southeastern U.S., confirmed that CSI incentivized sale representatives to offer buy one, get one free deals at the end of the quarter. This occurred by the Company setting "maddening" growth targets quarter after quarter, and "encourag[ing] a culture of figure out how to get it done no matter what."
- 62. Consistent with the allegations in the *qui tam* action, CW7, who worked at the Company from 2010 until 2012, most recently as a District Sales Manager in Ohio, also confirmed that sales representatives routinely offered buy so many, get so many free deals to customers, including buy 6, get 1 free deals.
- 63. CW10, another District Sales Manager in Florida, who worked at the Company from 2014 to 2015, regarded the buy one, get two free type deals she as a type of *quid pro quo*. According to CW10, sales reps would hold daily conference calls to

discuss what type of bundle offers to offer to which accounts in order to meet their sales targets. The offers were individualized according to the account, and CW10 confirmed that CSI offered buy three get three and buy three get two deals, which were approved by the regional sales manager. CW10 explained that money was no object when it came to making a sale happen, that sales reps were instructed to do whatever it took to obtain sales.

- 64. CW11, a District Sales Manager in the Boston area from 2010 to 2013, again identified Jim Breidenstein as a key orchestrator of "shady" sales practices, who, in spite of the Company's good product, implemented unethical practices purely to drive sales numbers. CW11 also confirmed the practice of offering buy so many, get so many free deals, which were always offered at the end of the quarter.
- 65. CW12, a District Sales Manager in Alabama from 2012-2014, further confirmed that these sort of deals were "absolutely" offered every quarter, with the end of the quarter being all about making the numbers. In reference to bundle deals, CW12 stated that "it was always buy this number, get this many free, a lot of changing out old product for new . . . that was a very common practice." Better and more frequent deals were offered to Office-Based Labs ("OBLs"), which were labs capable of performing procedures that used CSI products, owned independently by physicians. Given the obvious purchasing potential of OBLs, these offices became prime targets for illegal sales practices at CSI, which will be addressed in further detail below.
- 66. The wide-spread use of kickbacks in the form of give-aways of CSI's main product line was also confirmed in the *qui tam* action, which explained how various other

free products were offered to boost sales. For example, CSI's sales representatives offered St. Joseph's Regional Medical Center in New Jersey, Kootenai Medical Center in Idaho, and Walla Walla General Hospital in Washington, both a "free" Stealth device and a "free" saline infusion pump, a total kickback of \$8,390. CSI offered Kadlec Medical Center in Washington that same deal, plus free ViperWire Advanced Guide Wires and Lubricant, a kickback valued at \$10,730. CSI also offered Walla Walla General Hospital two "free" boxes of Asahi guide wires if Walla Walla purchased two other boxes of Asahi guide wires. *qui tam* action ¶71.

- 2. <u>CSI Orchestrates Practice-Building Through Referrals For Physicians That Use CSI's Devices</u>
- 67. CSI also offered valuable consideration to physicians in the form of patient referrals. In return for these referrals, the physicians to whom the patients were referred would use CSI's PAD Devices on those patients. Absent CSI's referral kickbacks, the physicians would have needed to expend their own resources to attract new patients—but also would have been far more likely to use other, less expensive procedures instead of being beholden to CSI.
- 68. CSI orchestrated this illicit kickback program by instructing its sales representatives to make sales calls to physicians and other health care providers who did not use CSI products—like podiatrists, nephrologists, wound care centers, home care nurses, dialysis techs, family-care doctors, orthopedic clinics, diabetes nurses, and senior citizen support organizations—but who could refer their patients to the cardiologists and vascular surgeons who did use CSI's PAD Devices.

- 69. CW1 confirmed that CSI "absolutely" targeted third-party physicians, such as podiatrists, nephrologists, family-care doctors, and others, to refer patients to physicians who would use CSI devices in return for these referrals. More than the ability to secure new accounts, CW1 stated that having third party physicians refer patients to existing CSI customers was also common, as it increased volume for the CSI device user, and that CSI typically hired per diems to conduct such referral marketing at third-party physician offices.
- 70. CW2 explained that Company training and marketing materials existed that were specifically designed for referral marketing, and recounted numerous instances of sales reps visiting third party physicians with marketing materials designed to drive referrals for existing CSI customers. Moreover, CSI would pay for dinners and invite an existing customer, along with two or three internal medicine doctors and podiatrists. Frequently, as the physicians themselves knew the busy internal medicine doctors and podiatrists in their area, the Company simply asked customers with large accounts who they wanted to refer to them, and targeted its referral marketing to those individuals.
- 71. CW4, who was personally involved in referral-marketing prior to becoming a full-time salaried salesperson, would introduce podiatrists, family doctors, and cardiologists at lunch-time meetings at physicians' offices, where potential referrers would be familiarized with CSI devices and their use, such that they became more comfortable when referring patients to CSI customers. Once CSI sales representatives arranged these referrals, they gained the loyalty of the cardiologists and vascular surgeons receiving the referrals.

- 72. CW13, who worked for CSI as a District Sales Manager in the Colorado and Wyoming area from 2011 to 2014, recounted that referral programs were typically disguised as educational programs for the referring doctor, but that at the end of these educational sessions CSI always let the doctors know of physicians in the area who could treat the referring doctor's patients, and who would be existing users of CSI's products.
- 73. The statements from these witnesses are consistent with the allegations of the *qui tam* action, which alleged that Gary Hall, a CSI sales representative, as stating, "I need [Podiatrists] to refer cases . . . [One podiatrist] basically has 4 reads for Monday that he is willing to give to one of my Docs"—i.e., cardiologists and vascular surgeons. "In one week I got 1 new Pod[iatrist] for 8 cases per month and now this new Pod[iatrist] has 4 reads and patients to funnel to my Doc . . . I don't want to say its [*sic*] like shooting fish in a barrel. . . . but it kinda is." *Qui tam* action ¶ 75.
- 74. The *qui tam* action also confirmed that CSI touted the financial benefits of performing more PAD screenings to referring physicians, who would in turn drive more patients to physicians who used CSI's PAD Devices. CSI marketed an "Equation for Success" to referring physicians, showing them that they could realize an additional \$50,000 per year in income simply by performing two more screenings per day. *Qui tam* action ¶ 75.
- 75. As set forth in the *qui tam* action, CSI knew that it could "not conduct practice building" and was well-aware of the "inducement risk" in such activities as described above. However, instead of avoiding such activities, CSI encouraged its sales representatives to conceal their improper activities by exhorting them that "email,

materials etc. . . . must not contain words or statements that someone could misinterpret as practice development." *Qui tam* action ¶ 76.

- 76. Regardless of its careful internal phraseology, CSI nevertheless viewed these activities as practice development for physicians who would use CSI's PAD Devices. According to the *qui tam* action, John Wilhelmy, a CSI Regional Sales Manager, openly praised one CSI sales representative for hosting "Multiple Referral Marketing Dinner events EXECTED [*sic*] to drive new business in the Vegas area." *Qui tam* action ¶ 77.
- 77. This referral-based marketing was a thinly disguised kickback program designed specifically to reward physicians who would use CSI devices in return for these referrals. These referrals violated the Anti-Kickback Statute, which prohibits the paying of kickbacks and similar *quid pro quos* to physicians to induce the purchase of a company's products as well as the provision of things of value to a physician for the purpose of inducing that physician to refer health services.
 - 3. <u>CSI Offered Assistance To Physicians Who Want To Open</u> Outpatient Labs And Who Return The Favor By Using CSI Devices
- 78. Office-Based Labs, or "OBLs," are out-of-hospital labs that are capable of performing the procedures that use CSI devices. These physician-owned labs allow physicians more autonomy as well as the ability to capture more of the income and profits from the procedures they perform, but require substantial start-up and management costs—often exceeding \$1 million in each new OBL—which many physicians find difficult to surmount. As confirmed in the *qui tam* complaint, CSI,

realizing the profit potential inherent in more physicians owning their own OBLs, funneled kickbacks to physicians starting up their own OBLs through National Cardiovascular Partners ("NCP"), an organization that joins with and assists physicians and hospitals in opening and managing OBLs.

- 79. The *qui tam* action explained that CSI has a cooperative relationship with NCP and offers NCP's services to regular users of CSI devices who wish to open and manage OBLs. Thus, CSI funneled physicians to NCP and then, to reward CSI, NCP encouraged its OBLs to use CSI's PAD Devices. *Qui tam* action ¶ 79-81.
- 80. The *qui tam* action also alleged that CSI offered kickbacks to physicians opening OBLs through substantially more favorable contracting terms. Whereas normally CSI demands upfront payment for its PAD Devices and does not accept returns of expired or unused product, CSI offered physicians opening OBLs (i) consignments of products, so that the physician did not incur the substantial upfront costs, and (ii) return or replacement of expired products. *Qui tam* action ¶ 82.
- 81. Practices similar to those alleged in the *qui tam* action were corroborated by multiple Confidential Witnesses. For example, CW1 confirmed that CSI helped doctors open OBLs by giving them financial assistance, and stated that the fact these were "getting kickbacks" made them "big CSI doctors."
- 82. CW2 also discussed similar kickbacks offered to CSI's OBL customers. Specifically, CW2 explained that not only did OBL physicians not have to pay for the two ancillary devices that must be used with the Stealth device, which hospitals did have to pay for, OBLs were also offered free boxes of the Asahi guide wires which are used in

connection with a Stealth device. CW2 noted that the practice was very profitable for CSI because outpatient labs were physician owned, and unlike hospitals, allowed the physician-owners to profit through reimbursements and therefore encouraged the physicians to over-use and buy large quantities of CSI's devices. Indeed, CW2 recounted instances where an OBL could treat ten patients a day, and noted that it was "staggering" how much money the doctor could make. Since OBLs were a growing phenomenon, CSI sought to exploit the opportunity, and in areas like Florida, the Company began steering all of its business towards OBLs. Finally, CW2 recalled that it was company policy to be a resource to physicians starting OBLs in order to secure their loyalty, and identified Paul Tyska, currently CSI's Director of Market Development, as having held the position of VP of Outpatient Labs, responsible for travelling to meet with physicians that were considering opening up their own outpatient labs. At these meetings, which would sometimes occur over dinner, Tyska would offer his expertise to ease the process of opening a lab, as well as connections to sources for cheaper equipment and other support. CW2 explained that CSI worked with partners who would provide financing, and specifically told physicians interested in opening OBLs that it could get them financing. When asked, CW2 commented that it would not be surprising if direct financial assistance was offered to these physicians.

83. CW6, a Regional Sales Manager who worked for the Company from 2009 until late 2012, and who was terminated because he questioned the unethical practices being implemented by VP of sales Jim Breidenstein, further confirmed the widespread use of kickbacks to secure business from OBLs. Not only did CSI encourage the

unnecessary use of its devices at OBLs in order to drive more purchases from them,
OBLs were prime targets for offers of free product and large discounts on bulk purchases.
CW6 again identified Paul Tyska as having been responsible for helping set up OBLs.
CW11, based in the Northeast, separately confirmed that the Company was encouraging physicians to open OBLs, and that the incentive to do so was so great because there were sales reps making their entire quarterly quotas on the basis OBL business alone.

- 84. Finally, CW14, a District Sales Manager in New York from 2012-2013, stated that CSI provided consulting services to physicians to build OBLs. Specifically, CSI developed a "total management solution" whereby if a physician was thinking about opening up an OBL, CSI would act as a consultant, and bring the physician together with the companies that would build the center, supply everyday disposables such as toilet paper and gloves, and would join together with other suppliers such as Bard, a large manufacturer of vascular stents, to obtain preferred pricing on such items as arterial balloons or stents. CSI itself would also offer the newly established OBL discount pricing on its devices.
- 85. By orchestrating enormously valuable assistance and funding to physicians starting their own OBLs, who would then direct *quid pro quo* purchases CSI's way, CSI used barely disguised kickbacks to induce purchases of its product, and as a result violated the anti-kickback statute.

E. <u>CSI Inflated Sales Figures By Manipulating Sales Orders And Promoting Unnecessary Uses</u>

- 86. During the Class Period, CSI's reported sales figures of its PAD Devices relied heavily on encouraging physicians to engage in gratuitous uses of CSI's products in unnecessary procedures so as to drive purchases and to use multiple devices in a single procedure. CSI sales representatives also facilitated the wastage of existing product on the shelves and engaged in order manipulations through a quarterly practice wherein sales representatives would order an "exorbitant amount" of product at the end of the quarter and then return the product after quarter end.
- 87. These improper practices, driven by executives who pushed CSI's sales force to make the numbers "no matter what," took on many forms. In one instance, CW1 stated that prior sales representatives in the same area were paying kickbacks to a laboratory technician to discard catheters in the garbage, which pumped up sales as new catheters were reordered. The laboratory technician was paid \$200 to \$500 per catheter and the purpose of this scheme was to make the account appear to be a high volume account. In taking over the account, CW1 discussed these kickbacks with a supervisor, who told CW1 to continue this practice and launder the payments to the laboratory technician as expenses, which the supervisor would then approve. Confirming that similar practices existed elsewhere, CW4 likewise reported stories of CSI employees hiding things off of customers' shelves in order to secure more orders. CW4 also witnessed instances of inventory going missing in hospitals, only to be discovered months or years later hidden somewhere. In one instance, months after having left CSI,

CW4 received a call from a coronary manager months about a missing controller for the coronary device at a customer hospital. Upon arrival, CW4 found the eight-foot tall control tower hidden in a closet.

- 88. The most common, and the most systematically corroborated, method of inflating sales was that of encouraging unnecessary or gratuitous uses of CSI devices. CWs 1, 2, 10, and 12, all confirmed the existence of this practice in one form or another, and recounted numerous instances of sales representatives instructed to present the value proposition of, or, more simply, profit, that the physician stands to make from using CSI devices instead of other, more proven or known-to-be-effective treatments.
- 89. For example, CW2 recounted instances of physicians treating patients that did not need to be treated because they could get up to \$18,000 for simply turning on a CSI device. Worse, however, was the fact that CSI officials encouraged these practices. CWs 2, 6, and 13 each recounted the terms "two or three banger" or "double or triple banger", common parlance within the CSI sales force for getting a physician to use two or even three devices during one procedure.
- 90. CWs 1, 2, 10, and 12 also all recounted the systematic use of one particular sales tactic, where sales reps would show physicians in painstaking detail how much more they stand to earn by using CSI devices instead of other treatments. In particular, these four CWs recounted an in-house piece of software designed to calculate and then compare the ultimate reimbursement that the physician stood to earn from a CSI product versus what was possible from a competing product or traditional treatment. According to CW1, the software, known as the "Freedom Tool," allowed CSI reps to e-mail the

results of these comparisons directly to their customers, and was standard-issue for sales reps' laptops and iPads. CW2 recounted instances of patients that had nothing wrong with them being treated in order to reap these lucrative reimbursements, with the most opportunistic doctors bringing patients back multiple times for unnecessary treatments after CSI's reimbursement calculator showed them how much money could be made by doing so. CW12 stated that the value propositions, or how much more reimbursement a doctor stood to make if they picked a CSI atherectomy device in addition to a stent and balloon (as opposed to just a stent and balloon), was a serious focus for management, who encouraged sales reps to highlight the amount of reimbursement a physician would generate if they used an atherectomy device.

- 91. Furthermore, CWs 2 and 12 discussed how the Company focused on educating accounts regarding reimbursement. The Company wanted its customers to know they could get high reimbursement by using its devices repeatedly, and instructed sales reps to educate the customers accordingly, a practice that encouraged additional, unnecessary usage of the device in OBLs.
- 92. According to its former employees, these "educational" measures paid off for CSI. CW11, noting the frequency with which he heard the use of three devices in one procedure, commented that CSI was encouraging the use of multiple devices, when it was not necessary, especially in OBLs. CW14 stated that many doctors were using CSI devices in surgery centers in cases that did not justify that use, and that physicians were motivated to spin unnecessarily because of high reimbursement rates.

93. Even now, CSI maintains on its website a complete "Reimbursement" section, detailing the reimbursement codes, schedules, and corresponding CSI devices, with separate guides for Peripheral and Coronary procedures.

REIMBURSEMENT

Peripheral Reimbursement

- · Coding Guide
- · Final 2015 Physician Payment Schedule
- · Final 2016 OPPS Peripheral
- Final 2016 IPPS Peripheral
- · Hospital Outpatient Reimbursement Quick Guide
- · Hospital Inpatient Reimbursement Quick Guide
- · Office Based Lab Payment (OBL) Quick Guide
- · Physician Facility Reimbursement Quick Guide
- · Ambulatory Surgical Center (ACS) Reimbursement Quick Guide

Coronary Reimbursement

- · Coding Guide
- · Final 2015 Physician Payment Schedule
- Final 2016 OPPS Coronary
- Final 2016 IPPS Coronary
- Hospital Outpatient Reimbursement Quick Guide
- · Hospital Inpatient Reimbursement Quick Guide
- · Physician Facility Reimbursement Quick Guide

Source: Cardiovascular Systems. Inc. website, reimbursement section.

94. The last sales-inflation practice, that of shipping and then returning unneeded product, was revealed by CW9, who was a shipping and receiving clerk at CSI's New Brighton, Minnesota office from 2011 to 2013, responsible for shipping and receiving PAD Devices. According to CW9, CSI's shipping and receiving would have to increase their production by over 100% at the end of the quarter as sales representatives would double or triple the orders that they normally made. Becoming suspicious that the sales were fraudulent or otherwise manufactured after seeing returns of a significant number of products that CW9 had personally shipped, CW9 conducted a test by marking the boxes and units with stars. CW9 found that during these periods of peak-shipments, over 95% of the boxes on which CW9 had placed stars would come back as returns —

never even opened. CW9 confirmed this by noting that the tape, which CW9 had personally applied, had not been disturbed.

- 95. CW9 added that there was no need to inform management what was going on because management was orchestrating the scam. Specifically, CW9 stated that sales inflation practices and fabricated shipments were directed and supervised by Padmini Natarajan, a long-time employee of over nine years, and currently the Senior Director of Customer Operations at CSI. Indeed, frequently at quarter-end, Natarajan would come to down to shipping and instruct that "huge" orders of up to 15-20 units would need to go out right away. CW9 believed this was to show a surge in sales and help the stock by making CSI's publically released numbers look better as these orders would add sales for the quarter.
- 96. By encouraging the intentional wastage of viable product, the unnecessary use of CSI devices in order to gain reimbursement, and ordering large numbers of product at each quarter's end and later returning those same orders, the Company artificially inflated its sales numbers, rendering the Company's Class Period revenues false and misleading.

VI. <u>ADDITIONAL SCIENTER ALLEGATIONS</u>

97. As alleged herein, Defendants knew or disregarded with deliberate recklessness that the public documents and statements they issued and disseminated throughout the Class Period were materially false and misleading and they knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements. Indeed, Defendants, by virtue of their receipt and knowledge of information

reflecting the true facts regarding CSI's illegal sales practices regarding PAD Devices, their control over, and/or receipt and/or modification of CSI's materially incomplete, false and misleading misstatements and/or their access to inside information concerning CSI and its illegal sales practices for PAD Devices, knowing or recklessly participated in the fraudulent course of conduct alleged herein. Indeed, the fraudulent scheme described in this Complaint could not have been perpetuated over such a substantial period of time or over such widespread geographic locations, without the knowledge and complicity, or at minimum reckless disregard, of the personnel at the highest level of the Company, including CFO Betterley and CEO Martin.

- 98. Martin and Betterley were the Company's highest executives, deeply involved in CSI's daily operations and had access to all material information regarding the Company's core operations, including such critical products as the PAD Devices. As such, they had knowledge of all material facts regarding CSI's core PAD Device sales business or at the very least had full and unfettered access to this same information. Martin and Betterley therefore knew or were severely reckless in disregarding the fact that adverse facts specified herein had not been disclosed to, and were being concealed from (in order to mislead), the investing public.
- 99. Further, as noted above, the sale of CSI's PAD Devices generates "substantially all" of the Company's revenue accounting for an average of more than 88% of the Company's revenues during the Class Period Given the crucial importance of PAD Device sales to CSI's operational and financial success, the sales figures and the illegal and illicit methods employed to achieve those sales em were among CSI's most

important internal metrics, a subject of intense market scrutiny and concern, and a topic on which Defendants made numerous public statements throughout the Class Period. As such, Martin and Betterley were plainly aware of the means by which the Company's core products were sold – namely, through illegal kickbacks, impermissible off-label marketing, and fabricating non-existent sales. Indeed, as CFO, Defendant Betterley was specifically responsible for monitoring and understanding how CSI generated revenues from its core products – *i.e.*, the PAD Devices – and therefore knew or was reckless as to the fact that CSI did it through such illegal sales tactics as off-label marketing and physician kickbacks.

- 100. Further, on multiple calls with investors and analysts, Martin and Betterley repeatedly discussed CSI's sales management team and, in particular, two key figures at the heart of CSI's fraud: Executive Vice President of Sales & Marketing Kevin Kenny (currently the Company's COO) and Senior Vice President of Sales Jim Breidenstein, who was fired as a part of the Company's sales restructuring in the wake of the DOJ investigation and *qui tam* suits. Moreover, Martin and Betterley specifically tied the hiring of these individuals to the Company's growth prospects. To cite just a few examples:
 - (a) On an October 6, 2011 analyst call, Martin trumpeted the recent hiring of Kevin Kenny, stating that his addition meant "many upgrades to our Sales and Marketing organization and our programs are in progress[]," that "[t]hese initiatives include management and professional staff additions and changes, upgrades in customer programs, *including physician education and training*." He added, "[t]hese changes are necessary to build the *foundation for higher growth* in the future but are disruptive initially," and assured investors that Kenny had

- "more than 20 years of medical device industry experience," and possessed "the management skills to bring out the best in our sales staff." (emphasis added). Responding to analysts' questions, he stated, "Kevin brings in his systems and process and get -- puts us in a position to scale over the coming years," and "Kevin Kenny is an individual that, quite frankly, we just couldn't have afforded a year ago, but we've got him now as an investment." Confidently, Martin predicted with amazing prescience that with Kevin on board, "we will have double-digit growth at year-end."
- (b) On a November 2, 2011 analyst call, Martin praised the work his new hire has done in the five months since he joined the company. In response to an analyst's question over whether the company would hire more top executives, Martin stated, "We're done. Kevin's done a great job. He's really reformulated management, programs, process. He's professionalizing this commercial organization. And it's a nice add. We've got key company assets in our Stealth technology, in our scientific build, in our coronary franchise that's on the up and come. Quality and regulatory has always been an earmark of this organization. And we have really controlled expenses on the back of our commercial team, but now in light of some of the other strengths including technology and science it is time to position our commercial organization for scale. So the investment in Kevin and in the new management, in the new processes, in the new medical education, it is going to show in the forward quarters and another indicator for second half fiscal growth."
- (c) On a February 7, 2012 analyst call, Martin again affirmed the company's "investment in Kevin Kenny." Then, in response to an analyst's question over how his sales force was transitioning to "go after" OBLs, Martin stated, "[Kenny's] blue chip business practices are being installed now. They showed last quarter and that's great. . . . And then, the play here is productivity. It won't be about massively expanding the footprint. It'll be about targeting those high volume institutions *on both peripheral and coronary*, whether that be in the hospital or the office-based, and servicing them in a way that

- we get really great productive metrics on our 78%-plus margin device." (emphasis added).⁴
- (d) On the May 2, 2012, Q3 2012 earnings call, Martin again touted Kenny's experience, as well as the addition earlier that year of Jim Breidenstein, stating, "[i]n January we brought on Jim Breidenstein as VP of Sales who had five years at Kyphon and success with growth and making that procedure mainstream."
- (e) On an October 30, 2012 analyst call, in response to an analyst's questions about how the Company's forthcoming quarter guidance trumped had expectations by so much, Martin stated, "Yes, we are driving utilization rates up in all of our targeted account bases -- top 50, top 200 office-based labs. . . . The second thing that's working is management. We've invested in new management. Kevin Kenny and Jim Breidenstein come with great experience, experience to scale, they're here to scale, and they're really activating the most important resource in the Company -- people. And then the third thing is, we've invested in medical education and we've really made great strides there. We're doing some really neat things for the physician operator."
- (f) On a January 30, 2013 analyst call, in response to an analyst's questions regarding enhancements to sales and marketing, Martin again praised the systems that Kenny and Breidenstein had installed since their entry into the Company, stating that these systems were "enhancements really we installed new management starting with Kevin Kenny about a year-and-a-half ago. And then, he's put in systems and process for management training and field sales training and every specific aspect of what we need to do in the adoption curve. Medical education has been a big hit, that was new."
- (g) On an August 6, 2014 analyst call, Martin affirmatively praised Kenny and Breidenstein in his preliminary remarks, stating, "after reporting a particularly strong revenue quarter and year, I need to recognize our commercial organization, led by Executive Vice President Kevin Kenny, Senior Vice President Jim Breidenstein, and Marketing Vice President David Veino.

⁴ This statement was made over a year and half before CSI obtained FDA approval for its coronary devices.

Under their direction and that of their peers and the team at our Texas and Minnesota headquarters, CSI has developed and recruited a best-in-class group of commercial professionals."

- 101. These two individuals, Kevin Kenny and Jim Breidenstein, who were directly responsible for sales at CSI and reported to the CEO, were identified in the *qui tam* action and by multiple Confidential Witnesses as being key orchestrators of CSI's scheme to illegal kickbacks and other illicit tactics to drive sales. *See qui tam* action ¶ 54, 55, 65. Defendants touted the work of both Kenny and Breidenstein, emphasizing they had been brought on by, worked closely with, and were in direct communication with the CEO, all while neglecting to inform CSI's investors that they were implementing an utterly unsustainable and in fact, illegal sales strategy which, if ever revealed, would tank the Company's stock price.
- 102. CW1, who identified multiple illegal sales practices as prevalent at CSI, prefaced his description of these practices by first naming Jim Breidenstein, stating that he was "known" to push his people to make their numbers any way they could. CW2, discussing presentations given at sales meetings where managers encouraged sales staff to give free product offers and bundle deals, stated that Breidenstein attended at least one such meeting, but was careful to never put anything in writing linking himself to the free products. CW3, a former senior executive, discussed how Breidenstein was brought on just as it was getting harder for CSI to meet numbers, and noted that Breidenstein pressured sales reps to secure "quid pro quo" sales from doctors that came to CSI training courses. CW3 also noted that Breidenstein was brought in by Kevin Kenny, who, though

he came across as an honest person, was in fact so much the opposite, that it was shocking how untrue this perception of legitimacy was.

- CW6 specifically stated that he was terminated by the Company after pushing back on Breidenstein's unethical marching orders. CW6 also confirmed that CSI began to make a turn for the worst when it hired Kenny, who in turn brought in Breidenstein. CW6 noted that, while it was a good thing Breidenstein has been fired, Kenny remains a part of the problem, and has avoided negative attention by remaining in the shadows while putting someone else in the spotlight in order to take the focus off him. CW14 noted that though the sales team was already combating market skepticism about the Company's PAD devices through being clinically astute, Breidenstein, when he arrived, approached the business not from a quality or effectiveness perspective, but treated it entirely like a "numbers game," that had to be played by selling the product as aggressively as possible, without paying proper attention to the clinical data and use case. CW11 further confirmed that the Breidenstein was "shady," and that Kenny, as his direct superior, was very likely aware of what Breidenstein was doing. Moreover, CW11 noted that management lacked ethics after Breidenstein's installation, and that it was shocking Breidenstein could get another job after he had been fired from CSI.
- 104. Given senior managements' close relationship with and repeated praise of the sales tactics implemented by Kenny and Breidenstein it is clear that Defendants knew or recklessly ignored the illegal activities these two CSI officials had implemented in order to drive quarter after quarter of double-digit sales growth.

A. Suspicious Stock Sales By CEO Martin and CFO Betterley During The Class Period

- 105. In addition, both Martin and Betterley engaged in stock sales during the Class Period that were suspiciously timed and dramatically out of line with their prior trading practices. As a result of these Class Period trades, Martin and Betterley profited from the artificial inflation embedded in the trading price of CSI stock caused by their false and misleading statements and omissions to investors during the Class Period. The Class Period sales of CSI stock by Martin and Betterley were highly unusual and suspicious as measured by (i) the total amount and percentage of shares sold, (ii) the contrast with Martin and Betterley's own prior trading history, and (iii) the timing of the sales. Martin and Betterley's sales therefore raise a strong inference of scienter.
- 106. To evaluate Martin and Betterley's selling activity, Plaintiffs used the publicly-available trading data that Martin and Betterley were required to report to the SEC on Form 4. Plaintiffs analyzed the trading by Martin and Betterley during the Class Period and then compared that to the over two-year period immediately preceding the Class Period beginning on May 25, 2009 and ending September 11, 2011 (the "Control Period"). The Form 4s filed during the Class Period and Control Period are hereby incorporated by reference.
- 107. To analyze Martin and Betterley's stock sales, Plaintiffs calculated the total sales by each, together with the cash proceeds from such sales, during the Control and Class Periods. Those totals were then compared. Martin and Betterley's specific trading dates were also evaluated compared to Corrective Disclosure dates. All of these analyses

reveal that Martin and Betterley's Class Period sales were extremely large, highly unusual, and suspicious.

108. The number of shares sold and the net proceeds from such sales during the Class Period by Martin and Betterley were extraordinarily large compared to the Control Period.

	Control Period		Class Period	
Person	Number of Shares Sold	Net Proceeds	Number of Shares Sold	Net Proceeds
Martin ^{5,6}	89,709	\$974,935	666,903	\$17,672,752
Betterley ⁷	20,626	\$221,745	147,781	\$3,931,772
Totals	110,335	\$1,196,680	814,684	\$21,604,524

109. Martin and Betterley's Class Period stock sales were not only large in absolute terms, but also inconsistent with Martin and Betterley's own prior selling activity during the Control Period.

110. Collectively, Martin and Betterley increased their stock sales more than from 110,335 shares during the Control Period to more than 814,684 shares during the Class Period – a startling increase of *more than 700%*. Taken individually, Martin and Betterley's sales both increased sharply. During the Class Period, Martin increased his sales six-fold from 89,709 to 666,903 shares. Betterley's sold share volume also increased significantly, from 20,626 shares sold during the Control Period to over 147,781 during the Class Period.

⁵ Excludes a May 30, 2013 withholding of 25,099 shares used to satisfy taxes or exercise price payment.

⁶ Trading prices rounded from Form 4s to the nearest one-hundredth.

⁷ Trading prices rounded from Form 4s to the nearest one-hundredth.

- 111. The contrast between Martin and Betterley's sales during the Control Period and the Class Period is even more striking when measured in dollars.

 Collectively, Martin and Betterley's sales increased more than *eighteen-fold* or more than *1,800%* from the Control Period to the Class Period, from approximately \$1,196,680 million during the Control Period to over \$21,604,524 million during the Class Period. Separately, Martin's trading increased exponentially, more than 18 times from \$974,935 during the Control Period to \$17,672,752 during the Class Period.

 Betterley's individual sales increased more than 17 times from \$221,745 during the Control Period to \$3,931,772 during the Class Period.
- 112. Martin and Betterley's sales of stock were even more suspiciously timed because they sold a vast number of shares between the filing of the *qui tam* action on July 15, 2013 and the disclosure of the DOJ investigation on May 9, 2014. During this time period, Martin sold 430,307 shares netting more than \$12.4 million in proceeds. Also during this time period, Betterley sold 45,930 shares netting more than \$1.1 million in proceeds.
- 113. While some of Martin and Betterley's stock sales were pursuant to Company trading plans, this provides no safe harbor as CSI's trading plans had been the target of government investigations in the past. For example, an April 24, 2013 Wall Street Journal article entitled *Directors Take Shelter in Trading Plans*, highlighted the alleged use of trading plans by a CSI corporate director to sell 83% of the stock owned by one of his investment funds, ending his selling just six days before a disappointing earnings announcement. On April 30, 2013, just a week after the article, the U.S.

Attorney's Office for the Eastern District of New York issued subpoenas to CSI launching a criminal investigation to determine whether the corporate director had been misusing trading plans to cover up illegal insider trading. On June 7, 2013, CSI filed a Form 8-K with the SEC announcing that SEC began its own investigation into the CSI director's trades.

Throughout the Class Period, Martin and Betterley were able to, and did, 114. control the contents of the Company's SEC filings, reports, press releases, and other public statements. Martin and Betterley also signed certifications pursuant to the Sarbanes-Oxley Act of 2002 in CSI's annual and quarterly reports filed throughout the Class Period, which contained false and misleading statements of material fact. Martin and Betterley were provided with copies of, reviewed and approved, and/or signed such filings, reports, releases, and other statements prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Martin and Betterley were also able to, and did, directly or indirectly, control the conduct of CSI's business, the information contained in its filings with the SEC, and its public statements. Moreover, they made or directed the making of affirmative statements to the investing public, and participated in meetings, conference calls, and discussions concerning such statements. Martin and Betterley knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations that were being made were then false and misleading.

VII. THE TRUTH EMERGES

- 115. The truth regarding the Company's widespread scheme to inflate sales and growth figures through the systematic employment of illegal sales tactics emerged gradually through a series of partial revelations.
- 116. On May 9, 2014, investors first began to learn that something was amiss at the Company. In a Form 8-K Current Report signed by Martin and Betterley (the "May 9, 2014 Form 8-K"), Defendants disclosed that CSI had received notice that the DOJ was investigating the Company "to determine whether the Company has violated the False Claims Act, resulting in the submission of false claims to federal and state health care programs, including Medicare and Medicaid." Defendants further disclosed that the DOJ had served a Civil Investigative Demand for written interrogatories and document requests. Nevertheless, at the same time, Defendants continued to falsely reassure investors of their legal compliance, stating that CSI "maintains rigorous policies and procedures to promote compliance with the False Claims Act and other regulatory requirements."
- 117. Recognizing that their illegal sales and marketing tactics had to subside with the increased public focus and government investigation, Defendants undertook to expand CSI's sales force in order to both maintain CSI's artificially high sales and growth figures and continue to hide their fraud from public view. On October 29, 2014, the Company announced this sales force expansion. While the expansion temporarily boosted sales, it created a significant increase in the Company's selling, general and administrative expenses, starting CSI's third fiscal quarter of 2015, as CSI attempted to

maintain its sales revenue. These expenses caused significant losses for the Company as expenses jumped from \$32.6 million in the second quarter of fiscal year 2015 to \$39.4 million the following quarter.



Source: SEC Form 10-Q, dated February 2, 2016 Source: SEC Form 10-Q, dated November 6, 2015 Source: SEC Form 8-K, dated August 5, 2015 Source: SEC Form 10-Q, dated May 5, 2015 Source: SEC Form 10-O, dated February 6, 2015

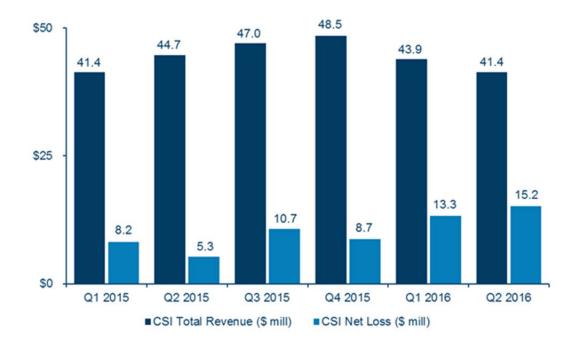
118. In connection with this sales force restructuring, and demonstrating that it was due to the increased scrutiny on CSI's illegal sales tactics resulting from the DOJ investigation and *qui tam* suit, CSI quietly terminated the employment of a central character in those same illegal practices, Jim Breidenstein, in mid-2015. Indeed, one former employee, CW8, a Regional Sales Manager in Florida from 2015-2016, noted that CSI became a different place in the wake of Mr. Breidenstein's departure. However, as set forth below, CSI's efforts to restructure and increase its sales force could not make

up for the loss of such a crucial sales and revenue driver as their illegal sales activity. As a result, the financial performance of the Company gradually declined.

- Defendant Betterley, the Company stated "[a]s previously reported" the DOJ was "investigating the Company to determine whether the Company has violated the False Claims Act ("FCA")." The 8-K further stated that the *qui tam* complaint "underlying the [DOJ's] investigation was unsealed" that "allege[d] various causes of action under the federal FCA and several state FCA provisions relating to alleged kickbacks and off-label promotion of medical devices and that this alleged conduct has resulted in false claims being submitted to obtain payment or reimbursement." Yet again, however, Defendants continued to falsely reassure investors of their legal compliance, stating that CSI "maintains rigorous policies and procedures to promote compliance with the [False Claims Act] and other regulatory requirements and intends to vigorously defend this lawsuit, should it proceed."
- 120. On April 29, 2015, the Company announced its financial results for the third quarter of fiscal year 2015, disclosing that its sales force expansion which was implemented in order to make up for and mask the loss of sales due to decreased illegal activity created a jump in expenses causing the Company to incur significant losses.
- 121. On August 5, 2015, investors received a growing sense of the "chill" on Defendants' illegal practices resulting from the DOJ investigation when the Company announced disappointing results for the fourth quarter of fiscal 2015. On that day, CSI reported revenues of \$48 million, which was below consensus expectations of \$50.1

million. As CEO Martin acknowledged in a Form 8-K filed with the SEC on August 5, 2015, CSI's "revenue was slightly below our expectations" – however, he falsely attributed that to the "sale force expansion...[falling] short of our targets." The Company likewise noted that "revenue was slightly below guidance" and misleadingly claimed that was due to "sales headcount being below the levels targeted in the company's sale optimization and expansion plan during the quarter."

122. On October 7, 2015, the "chill" on CSI's main revenue driver – namely, the illegal sales tactics outlined herein – became more apparent when CSI reported disappointing preliminary financial results for the first quarter of fiscal year 2016. Indeed, CSI disclosed weaker than forecasted revenues of "approximately \$43.9 million," which was significantly below its previously issued guidance of \$48.5-\$50 million, and staggering expected losses of \$13.1 - \$13.9 million – an increase of approximately 60 – 70% over the prior quarter. CEO Martin acknowledged the disappointing results in CSI's October 7, 2015 press release – while still attributing it to sales force expansion issues. For example, Martin stated "as our recent results suggest, some aspects of the [sales force expansion] have been challenging." Martin further assured investors that, ultimately, "[w]e see no change in our multi-billion market opportunity" and that CSI would "capitalize on this opportunity and drive attractive double digit revenue growth and profitability in the future."



Source: SEC Form 8-K, dated January 21, 2016 Source: SEC Form 8-K, dated November 4, 2015 Source: SEC Form 8-K, dated August 5, 2015 Source: SEC Form 8-K, dated April 29, 2015 Source: SEC Form 8-K, dated January 28, 2015 Source: SEC Form 8-K, dated October, 29, 2014

123. On January 21, 2016, CSI announced yet another quarter of disappointing financial results, and the market finally realized that Defendants' purported "sales force expansion" would not suffice to make up for the loss of sales resulting from the decline in Defendants' illegal sales tactics resulting from the DOJ investigation. Indeed, on January 21, 2016, CSI announced second quarter of fiscal 2016 revenues of \$41.4 million – which was 3% below guidance range, a 4% decrease from the second quarter of fiscal 2015 and a nearly 6% decrease from the prior quarter.

VIII. LOSS CAUSATION/ECONOMIC LOSS

- 124. Each of the corrective disclosures set forth in the preceding section caused significant drops in the Company's stock price, which grew increasingly worse as the Company's expenses increased and revenue plummeted. By January 22, 2016, the day after the Class Period, CSI's stock had plunged precipitously to \$8.74 per share, down from its Class Period high of \$40.98 per share on April 9, 2015, a drop of nearly 80%. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the damages suffered by Lead Plaintiffs and the Class.
- 125. During the Class Period, Defendants engaged in a course of conduct which artificially inflated the price of CSI's common stock by misrepresenting, or failing to disclose that CSI sold its PAD Devices primarily thorough illegal and improper kickbacks and promoting the off-label sales and use of its medical devices in order to obtain reimbursement for non-FDA-approved indications and maximize profits through false and fraudulent statements.
- 126. Later, as the Company's prior false statements, misrepresentations, and fraudulent conduct were disclosed to the market, the prices of CSI's common stock fell as the prior artificial inflation dissipated from the market price of the stock. As a result of their purchases of the Company's common stock during the Class Period, Co-Lead Plaintiffs and other members of the Class suffered economic loss, *i.e.*, damages, under the federal securities laws. For purposes of alleging loss causation, the price decline in CSI common stock, as detailed herein, was a direct result of the nature and extent of the

materially false and misleading statements and omissions revealed to investors and the market, as follows:

- 127. On May 9, 2014, in reaction to the Company's announcement of the DOJ investigation into violations of the FCA, as set forth above, the price of CSI shares declined \$2.51 per share, or over 8%, from an opening of \$29.94 per share on May 12, 2014 (the next trading day), to close at \$27.43 per share that day.
- 128. On April 29, 2015, in reaction to the Company's announcement of disappointing financial results relating to the fraudulent and illegal practices alleged herein, as set forth above, the price of Company's stock fell \$4.88, or 14%, over the next two trading days on larger than normal volume, from a close of \$34.82 on April 29, 2015, to a close of \$29.94 on May 1, 2015.
- 129. On August 5, 2015, in reaction to the Company's announcement of disappointing financial results relating to the fraudulent and illegal practices alleged herein, as set forth above, the price of the Company's stock plummeted \$6.13, or 21%, the next day on volume nearly 15 times larger than the 10-day average, from a close of \$29.35 on August 5, 2015, to a close of \$23.22 on August 6, 2015.
- 130. On October 7, 2015, in reaction to the Company's announcement of disappointing financial results relating to the fraudulent and illegal practices alleged herein, as set forth above, the price of the Company's common stock plummeted \$3.01 or 18%, from a close of \$16.63 on October 7, 2015, to a close of \$13.62 on October 8, 2015.
- 131. Finally, on January 21, 2016, in reaction to the Company's announcement of disappointing financial results relating to the fraudulent and illegal practices alleged

herein, as set forth above, the price of Company shares declined \$3.72 per share, or nearly 30%, from a close of \$12.46 per share on January 21, 2016, to close at \$8.74 per share on January 22, 2016.

- 132. Each of the declines in the Company's stock price discussed above was statistically significant at a high level after taking into account changes on the same days in the overall securities market and in relevant industry indices. Furthermore, as set forth above, each of the price declines in CSI's stock is attributable to the disclosure of previously concealed information relating to the materially false and misleading statements and omissions alleged herein. The timing and magnitude of CSI's stock price declines negate any inference that the losses suffered by Plaintiffs and other Class members were caused by other changed market conditions, macroeconomic or industry factors, or Company-specific facts unrelated to Defendants' fraudulent conduct. As the truth about Defendants' fraud was revealed, the Company's common stock price declined, the artificial inflation came out of the price of the common stock, and Plaintiffs and other members of the Class suffered damages.
- 133. Indeed, based on the declines in revenues that the Company suffered in the wake of various partial corrective disclosures, including the announcement of the DOJ investigation, it appears that sales directly attributable to illegal activities can be estimated to amount to approximately 15% of CSI's total revenues if not higher. For example, from the Class Period high of \$48.5 million in revenues for the fourth quarter of fiscal 2015, revenues declined over the subsequent two quarters by more than \$8 million, as the Company's results declined due to the abandonment of its illegal sales practices.

IX. <u>DEFENDANTS' MATERIALLY FALSE AND MISLEADING</u> STATEMENTS AND OMISSIONS OF MATERIAL FACT

A. September 12, 2011 – Fiscal Year 2011 Annual Report

- 134. The Class Period begins on September 12, 2011. On that date, CSI filed its Form 10-K Annual Report for the fiscal year ended June 30, 2011 with the SEC (the "2011 Form 10-K"). Betterley and Martin signed the 2011 Form 10-K.
- 135. In the 2011 Form 10-K, the Company acknowledged that it was unable to market its PAD Devices for off-label uses, stating:

The PAD Systems received FDA 510(k) clearances in the United States for use as a therapy in patients with PAD. This general clearance restricts our ability to market or advertise the PAD Systems beyond this use and could affect our growth. While off-label uses of medical devices are common and the FDA does not regulate physicians' choice of treatments, the FDA does restrict a manufacturer's communications regarding such off-label use. We are not permitted to promote or advertise the PAD Systems for off-label uses. In addition, we cannot make comparative claims regarding the use of the PAD Systems against any alternative treatments without conducting head-to-head comparative clinical trials, which would be expensive and time consuming. If our promotional activities fail to comply with the FDA's regulations or guidelines, we may be subject to FDA warnings or enforcement action. If we determine to market the PAD Systems in the United States for other uses, for instance, use in the coronary arteries, we would need to conduct further clinical trials and obtain premarket approval from the FDA.

136. The statement in the 2011 Form 10-K in Paragraph 135 above that CSI is "not permitted to promote or advertise PAD Systems for off-label uses" was materially false and misleading when made because it failed to disclose that CSI had in fact done just that—promoted and advertised PAD Devices for off-label uses.

137. The 2011 Form 10-K also acknowledged and discussed the applicability of the FDCA, the federal Anti-Kickback Statute, and the False Claims Act to the Company:

Our operations will be directly, or indirectly through our customers, subject to various state and federal fraud and abuse laws, including, without limitation, the FDCA, federal Anti-Kickback Statute and False Claims Act. These laws may impact, among other things, our proposed sales, marketing, and education programs. In addition, these laws require us to screen individuals and other companies, suppliers and vendors in order to ensure that they are not "debarred" by the federal government and therefore prohibited from doing business in the healthcare industry.

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business. the statute has been violated. The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

The federal False Claims Act prohibits persons from knowingly filing or causing to be filed a false claim to, or the knowing use of false statements to obtain payment from, the federal government. Various states have also enacted laws modeled after the federal False Claims Act.

- 138. The statements from the 2011 Form 10-K in Paragraph 137 above were materially misleading when made because they did not disclose that the Company was in fact not in compliance with applicable laws.
- 139. The Company also attached its "CODE OF ETHICS AND BUSINESS CONDUCT" (the "Code of Ethics") as Exhibit 14.1 to the 2011 Annual Report. The Code of Ethics stated in relevant part (all emphases in original):

Bribery, kickbacks or other improper or illegal payments have no place in CSI's business.

* * *

Business Courtesies and Gratuities

CSI's policy is not to offer or accept kickbacks or bribes, or gifts of substantial value.

CSI Representatives may only exchange non-monetary and modestly-valued gifts that promote goodwill with our business partners and do not improperly influence others. We will accept only approved and widely available discounts and do not encourage, accept or exchange gratuities or payments for providing services to others.

. . .

Representatives must deal fairly and honestly with the Company's customers (including potential customers and Health Care Professionals or entities in a position to recommend or influence the purchase or use of Company products) and not take actions that are prohibited by applicable law or ethical standards.

. . .

The following general standards and principles should at all times guide our interactions with customers and Health Care Professionals:

- CSI will encourage ethical business practices and socially responsible industry conduct, and will not use any unlawful inducement in order to sell, recommend or arrange the sale, or prescription of its products.
- . . .
- Interactions should be focused on informing customers and prospective customers about products, providing scientific and educational information, and supporting medical research and education and should not, at any time, entice representatives of customers to place their own personal interests above those of the organizations they represent or the patients who will use or need the Company's products.
- CSI will not, directly or indirectly, offer or solicit any kind of payments or contributions for the purpose of obtaining, giving, keeping or rewarding business.

No Payments in exchange for business

Representatives may not make payments to customers or provide meals, travel expenses, entertainment, gifts, or other benefits to customers or Health Care Professionals in exchange for the customer's agreement to purchase products or services from the Company, or as a reward for the purchase of products or services, nor may Representatives provide benefits to a customer's friends, relatives, or organizations closely affiliated with the customer in exchange for or as a reward for such business.

- 140. The statements from the 2011 Form 10-K in Paragraph 139 above were materially false and misleading when made because they did not disclose that the Company relied on illegal and improper kickbacks to promote its PAD Devices to medical practitioners and drive sales of its PAD Devices.
- 141. The 2011 Form 10-K disclosed results of operations expressed as dollar amounts (in thousands) as follows:

Year Ended June 30,

	2011	2010
Revenues	\$ 78,780	64,829
Cost of goods sold	16,277	15,003
Gross Profit	62,503	49,826
Expenses:		
Selling, general and administrative	62,372	62,447
Research and development	8,940	10,278
Total expenses	71,312	72,725
Loss from operations	(8,809)	(22,899)
Interest and other income (expense)	(2,316)	(1,005)
Net loss	(11,125)	(23,904)

- 142. The statements from the 2011 Form 10-K in Paragraph 141 above were materially false and misleading when made because they did not disclose the fact that revenues from the sales of the Company's PAD Devices depended on CSI engaging in systematic, unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products.
- 143. The same Form 10-K specifically stated that "we expect our revenue to increase as we increase the number of physicians using the devices, and increase the usage per physician as we continue to focus on physician education programs, introduce new and improved products, and generate clinical data."
- 144. By stating that the Company expected revenues to grow through legitimate market uptake, specifically physician adoption and "educational programs," and by failing to disclose that a plan was in place to rely systematically on unsustainable kickbacks and persuading physicians to engage in unnecessary uses of its product, these

statements from the 2011 Form 10-K in Paragraph 143 above were materially false and misleading when made.

by the Sarbanes-Oxley Act of 2002, by Martin and Betterley, who certified that the 2011 Form 10-K "does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading" and that "the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant."

B. <u>October 6, 2011 – Q1 2012 Press Release</u>

- 146. On October 6, 2011, the Company issued a press release disclosing its preliminary first quarter 2012 financial results (the "Q1 2012 Press Release"), announcing "preliminary revenue of approximately \$18.7 million for the fiscal 2012 first quarter ended September 30, 2011, compared with \$18.2 million in the first quarter of fiscal 2011."
- 147. The statements from the Q1 2012 Press Release in Paragraph 146 above were materially false and misleading when made because they did not disclose the fact that revenues from the sales of the Company's PAD Devices depended on CSI engaging in systematic, unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products.

C. October 6, 2011 – Q1 2012 Earnings Call

- 148. On October 6, 2011, CSI held a conference call with analysts to discuss the Company's first quarter 2012 earnings (the "Q1 2012 Earnings Call"). Martin and Betterley participated in this call. Betterley stated that CSI announced "revenue for the first quarter of fiscal 2012 of approximately \$18.7 million, which is 3% greater than the \$18.2 million posted in last year's first quarter" and "[d]evice unit sales were similar to last year at nearly 5300 devices." Admitting that sales were lower than expected, Martin specifically attributed revenues to "short-term marketplace dynamics and transitions," and added that "Our Sales and Marketing organization is going through some beneficial adjustments to staffing and improved processes. As a result, we expect our revenues to grow substantially for the remainder of the year and achieve double-digit growth for the full fiscal year 2012 over fiscal 2011."
- 149. This was the same call in which Martin first touted the recent addition of Kevin Kenny, who he stated was introducing "many upgrades to our Sales and Marketing organization." These statements were materially false and misleading when made because they did not disclose the fact that the Company intended to commence a sales program consisting precisely of systematic and unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products. Indeed, the Company affirmatively misled the investing public by predicting—accurately—that investors shall soon see "double-digit" growth, but specifically attributing that predicted growth to "beneficial adjustments to staffing and improved processes," rather than the planned commencement of regulatory violations.

D. November 8, 2011 – Q1 2012 Form 10-Q

- 150. On November 8, 2011, the Company filed its Form 10-Q Quarterly Report for the first quarter of fiscal year 2012 with the SEC (the "Q1 2012 Form 10-Q"). The Q1 2012 Form 10-Q was signed by Martin and Betterley.
- 151. The Q1 2012 Form 10-Q disclosed the Company's results of operations expressed as dollar amounts (in thousands) as follows:

Three Months Ended September 30,

	2011	2010
Revenues	\$ 18,660	18,165
Cost of goods sold	 4,346	4,141
Gross Profit	 14,314	14,024
Expenses		
Selling, general and administrative	15,350	15,496
Research and development	 2,064	2,422
Total expenses	 17,414	17,918
Loss from operations	(3,100)	(3,894)
Interest and other, net	(759)	(374)
Net loss	(3,859)	(4,268)

152. The company accompanied these results with the following statement:

Revenue for the three months ended September 30, 2011 was impacted by several factors, primarily high customer demand for conversion to the new Stealth 360° PAD System and movement by some high-volume physicians from hospitals to office-based labs. Both of these developments consumed selling time and temporarily delayed sales as purchases transitioned between sites and product lines. The impact was heightened by changes made in sales and marketing to position us to scale for high revenue growth in the future, and by a general softness in PAD procedures.

153. The statements from the Q1 2012 Form 10-Q in Paragraphs 151 and 152 above were materially false and misleading when made because they did not disclose the

fact that revenues from the sales of the Company's PAD Devices was growing at least in part due to the effectiveness of the Company's newly implemented program of systematic, unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products.

154. The Q1 2012 Form 10-Q was accompanied by signed certifications, as required by the Sarbanes-Oxley Act of 2002, by Martin and Betterley, who certified that the Q1 2012 Form 10-Q "does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading" and that "the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant."

E. <u>February 7, 2012 – Q2 2012 Press Release</u>

- 155. On February 7, 2012, the Company issued a press release disclosing its second quarter 2012 financial results (the "Q2 2012 Press Release"), announcing "revenues in the second quarter rose to \$19.7 million, a 5 percent gain over revenues of \$18.8 million in the second quarter of last fiscal year."
- 156. The statements from the Q2 2012 Press Release in Paragraph 155 above were materially false and misleading when made because they did not disclose the fact that revenues from the sales of the Company's PAD Devices depended on CSI engaging in systematic, unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products.

F. February 7, 2012 – Q2 2012 Earnings Call

- 157. On February 7, 2012, CSI held a conference call with analysts to discuss the Company's second quarter 2012 earnings (the "Q2 2012 Earnings Call"). Martin and Betterley participated in this call. Betterley stated that "[f]or the second quarter of fiscal 2012 compared to a year ago, revenues grew 6% sequentially and 5% over the prior year to \$19.7 million" and "[o]ver 5,500 devices were sold in the quarter."
- 158. The statements from the Q2 2012 Earnings Call in Paragraph 157 above were materially false and misleading when made because they did not disclose the fact that revenues from the sales of the Company's PAD Devices depended on CSI engaging in systematic, unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products.

G. February 9, 2012 – Q2 2012 Form 10-Q

- 159. On February 9, 2012, the Company filed its Form 10-Q Quarterly Report for the second quarter of fiscal year 2012 with the SEC (the "Q2 2012 Form 10-Q"). The Q2 2012 Form 10-Q was signed by Martin and Betterley.
- 160. The Q2 2012 Form 10-Q disclosed the Company's results of operations expressed as dollar amounts (in thousands) as follows:

Three Months Ended December 31,

	 2011	2010
Revenues	\$ 19,718	18,756
Cost of goods sold	 4,560	3,972
Gross Profit	15,158	14,784
Expenses	·	
Selling, general and administrative	15,733	14,687
Research and development	3,084	2,114
Total expenses	 18,817	16,801
Loss from operations	(3,659)	(2,017)
Interest and other, net	(476)	27
Net loss	(4,135)	(1,990)

- 161. The Q2 2012 Form 10-Q specifically stated that the growth in revenue was "primarily from increased average selling prices." The statements from the Q2 2012 Form 10-Q in this Paragraph and Paragraph 160 above were materially false and misleading when made because they did not disclose the fact that revenues from the sales of the Company's PAD Devices was growing at least in part due to the effectiveness of the Company's newly implemented program of systematic, unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products.
- 162. The Q2 2012 Form 10-Q was accompanied by signed certifications, as required by the Sarbanes-Oxley Act of 2002, by Martin and Betterley, who certified that the Q2 2012 Form 10-Q "does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading" and that "the financial statements, and other financial information included in this report, fairly present

in all material respects the financial condition, results of operations and cash flows of the registrant."

H. May 2, 2012 – Q3 2012 Press Release

- 163. On May 2, 2012, the Company issued a press release disclosing its third quarter 2012 financial results (the "Q3 2012 Press Release"), announcing "CSI's revenues in the third quarter rose to \$21.2 million, an 8 percent increase over the second quarter of fiscal 2012, and a 5 percent gain over revenues of \$20.2 million in the third quarter of last fiscal year."
- 164. The statements from the Q3 2012 Press Release in Paragraph 163 above were materially false and misleading when made because they did not disclose the fact that revenues from the sales of the Company's PAD Devices depended on CSI engaging in systematic, unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products.

I. May 2, 2012 – Q3 2012 Earnings Call

- 165. On May 2, 2012, CSI held a conference call with analysts to discuss the Company's third quarter 2012 earnings (the "Q3 2012 Earnings Call"). Martin and Betterley participated in this call. Betterley stated that "[f]or the third quarter of fiscal 2012 compared to a year ago, revenues grew 5% and 8% sequentially over the second quarter of 2012 to \$21.2 million" and "[o]ver 5,800 devices were sold."
- 166. The statements from the Q3 2012 Earnings Call in Paragraph 165 above were materially false and misleading when made because they did not disclose the fact that revenues from the sales of the Company's PAD Devices depended on CSI engaging

in systematic, unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products\

167. During the call, an analyst questioned if the sales force restructuring and the way CSI was selling its products were the reason that revenue stabilized. Martin responded:

I do think that some of the hires that we made nine months ago have taken effect these past few quarters as we grew 6% and then consecutively here 8%. We're bringing in people who are appropriate for mainstream adoption as we enter in and try to make this procedure mainstream. We've got Kevin Kenny who has managed over 1,500 people. In January we brought on Jim Breidenstein as VP of Sales who had five years at Kyphon and success with growth and making that procedure mainstream . . . And just a couple of examples, we brought our sales team together for the first time under the --Kevin and Jim's leadership in January for education and motivation as an entire group.

168. The statements from the Q3 2012 Earnings Call in Paragraph 167 above were materially false and misleading when made because while touting CSI's new sales management, Martin did not disclose that the same management was implementing a sales strategy of illegal and improper kickbacks and off-label marketing of CSI's PAD Devices. Indeed, this false and misleading statement was made in direct response to a question specifically targeted at the Company's sales methods, and any answer other than an admission of illegality in its sales practices would have been false, as was the case here.

J. May 8, 2012 – Q3 2012 Form 10-Q

- 169. On May 8, 2012, the Company filed its Form 10-Q Quarterly Report for the third quarter of fiscal year 2012 with the SEC (the "Q3 2012 Form 10-Q"). The Q3 2012 Form 10-Q was signed by Martin and Betterley.
- 170. The Q3 2012 Form 10-Q disclosed the Company's results of operations expressed as dollar amounts (in thousands) as follows:

Three Months Ended March 31,

	 •	
	 2012	2011
Revenues	\$ 21,205	20,152
Cost of goods sold	 5,132	3,949
Gross Profit	 16,073	16,203
Expenses		
Selling, general and administrative	16,809	16,415
Research and development	2,985	1,780
Total expenses	 19,794	18,195
Loss from operations	 (3,721)	(1,992)
Interest and other, net	(470)	(392)
Net loss	(4,191)	(2,384)

171. The Q3 2012 Form 10-Q continued to attribute revenue increases to "increased average selling price as a result of the introduction of the Stealth 360°," a more expensive device than prior CSI products. These statements from the Q3 2012 Form 10-Q in this Paragraph and Paragraph 170 above were materially false and misleading when made because they did not disclose the fact that revenues from the sales of the Company's PAD Devices depended on CSI engaging in systematic, unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products.

172. The Q3 2012 Form 10-Q was accompanied by signed certifications, as required by the Sarbanes-Oxley Act of 2002, by Martin and Betterley, who certified that the Q3 2012 Form 10-Q "does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading" and "the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant."

K. <u>August 8, 2012 – Q4 2012 Press Release</u>

- 173. On August 8, 2012, the Company issued a press release disclosing its fourth quarter 2012 financial results (the "Q4 2012 Press Release"), announcing "CSI's fourth-quarter revenues rose to \$22.9 million, an 8 percent gain over the fiscal 2012 third quarter and up 6 percent over \$21.7 million in the fourth quarter of fiscal 2011."
- 174. The statements from the Q4 2012 Press Release in Paragraph 173 above were materially false and misleading when made because they did not disclose the fact that revenues from the sales of the Company's PAD Devices depended on CSI engaging in systematic, unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products.

L. <u>August 8, 2012 – Q4 2012 Earnings Call</u>

175. On August 8, 2012, CSI held a conference call with analysts to discuss the Company's fourth quarter of fiscal year 2012 earnings (the "Q4 2012 Earnings Call").

Martin and Betterley participated in this call. Betterley stated that "[f]or the fourth

quarter of fiscal 2012 compared to a year ago revenues grew 6% over the prior year and 8% sequentially to \$22.9 million" and "[n]early 6,300 devices were sold in the quarter."

176. The statements from the Q4 2012 Earnings Call in Paragraph 175 above were materially false and misleading when made because they did not disclose the fact that revenues from the sales of the Company's PAD Devices depended on CSI engaging in systematic, unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products.

M. September 10, 2012 – Fiscal Year 2012 Annual Report

- 177. On September 10, 2012, CSI filed its Form 10-K Annual Report for the fiscal year ended June 30, 2012 with the SEC (the "2012 Form 10-K"). Betterley and Martin signed the 2012 Form 10-K.
- 178. The 2012 Form 10-K also acknowledged and discussed the applicability of the FDCA, federal Anti-Kickback Statute, and False Claims Act to the Company:

Our operations will be directly, or indirectly through our customers, subject to various state and federal fraud and abuse laws, including, without limitation, the FDCA, federal Anti-Kickback Statute and False Claims Act. These laws may impact, among other things, our proposed sales, marketing, and education programs. In addition, these laws require us to screen individuals and other companies, suppliers and vendors in order to ensure that they are not "debarred" by the federal government and therefore prohibited from doing business in the healthcare industry.

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

The federal False Claims Act prohibits persons from knowingly filing or causing to be filed a false claim to, or the knowing use of false statements to obtain payment from, the federal government. Various states have also enacted laws modeled after the federal False Claims Act.

- 179. The statements from the 2012 Form 10-K in Paragraph 178 above were materially misleading when made because they did not disclose that the Company was not in compliance with applicable laws.
- 180. The 2012 Form 10-K disclosed results of operations expressed as dollar amounts (in thousands) as follows:

Year Ended June 30,

	2012	2011
Revenues	\$ 82,490	78,780
Cost of goods sold	19,216	16,277
Gross Profit	63,274	62,503
Expenses:		
Selling, general and administrative	66,366	62,372
Research and development	11,374	8,940
Total expenses	77,740	71,312
Loss from operations	(14,466)	(8,809)
Interest and other income (expense)	 (2,324)	(2,316)
Net loss	(16,790)	(11,125)

- average selling prices of PAD Systems." These above statements from the 2012 Form 10-K in this Paragraph and Paragraph 180 above were materially false and misleading when made because they did not disclose the fact that revenues from the sales of the Company's PAD Devices depended on CSI engaging in systematic, unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products.
- 182. The 2012 Form 10-K was accompanied by signed certifications, as required by the Sarbanes-Oxley Act of 2002, by Martin and Betterley, who certified that the 2012 Form 10-K "does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading" and that "the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant."

N. <u>October 30, 2012 – Q1 2013 Press Release</u>

- 183. On October 30, 2012, the Company issued a press release disclosing its first quarter 2013 financial results (the "Q1 2013 Press Release"), announcing "CSI's first-quarter revenues grew to \$23.3 million, a 25 percent increase over the first quarter of fiscal 2012."
- 184. The statements from the Q1 2013 Press Release in Paragraph 183 above were materially false and misleading when made because they did not disclose the fact that revenues from the sales of the Company's PAD Devices depended on CSI engaging

in systematic, unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products.

O. <u>October 30, 2012 – Q1 2013 Earnings Call</u>

- 185. On October 30, 2012, CSI held a conference call with analysts to discuss the Company's first quarter of fiscal year 2013 earnings (the "Q1 2013 Earnings Call"). Martin and Betterley participated in this call. Betterley stated that "[f]or the first quarter of fiscal 2013 compared to a year ago, revenues grew 25% to \$23.3 million" and "[m]ore than 6,400 devices were sold in the quarter."
- 186. The statements from the Q1 2013 Earnings Call in Paragraph 185 above were materially false and misleading when made because they did not disclose the fact that revenues from the sales of the Company's PAD Devices depended on CSI engaging in systematic, unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products.
- 187. During the call, Martin specifically cited new sales management, Kevin Kenny and Jim Breidenstein, as one of the reasons for CSI's revenue growth. Martin stated that they "come with great experience, experience to scale, they're here to scale, and they're really activating the most important resource in the Company—people."
- 188. The statements from the Q1 2013 Earnings Call in Paragraph 187 above were materially false and misleading when made because while touting CSI's new management, Martin did not disclose that in fact the growth was the result of an unsustainable sales strategy of illegal and improper kickbacks and off-label marketing of CSI's PAD Devices.

189. In response to an analyst's concern about the number of new customers dropping, Martin responded that:

One is, we're entrenching in the larger accounts. You know, we're doing that because we want to go where the patients are and the volume is, and we've got a great story now to go back into some of these accounts where there was doubters, with physicians two, three, or four—with the scientific data, the new technology, and make some gains in high-volume accounts.

190. The statements from the Q1 2013 Earnings Call in Paragraph 189 above were materially false and misleading when made because Martin did not disclose that CSI was "entrenching" in the larger accounts because physicians with large accounts received greater kickbacks from CSI.

P. November 8, 2012 – Q1 2013 Form 10-Q

- 191. On November 8, 2012, the Company filed its Form 10-Q Quarterly Report for the first quarter of fiscal year 2013 with the SEC (the "Q1 2013 Form 10-Q"). The Q1 2013 Form 10-Q was signed by Martin and Betterley.
- 192. The Q1 2013 Form 10-Q disclosed the Company's results of operations expressed as dollar amounts (in thousands) as follows:

Three Months Ended September 30,

	2	2012	2011
Revenues	\$	23,293 \$	18,660
Cost of goods sold		5,254	4,346
Gross Profit		18,039	14,314
Expenses			
Selling, general and administrative		20,023	15,350
Research and development		3,222	2,064
Total expenses		23,245	17,414
Loss from operations		(5,206)	(3,100)
Interest and other, net		(4)	(759)
Net loss and comprehensive loss		(5,210)	(3,859)

- 193. The statements from the Q1 2013 Form 10-Q in Paragraph 192 above were materially false and misleading when made because they did not disclose the fact that revenues from the sales of the Company's PAD Devices depended on CSI engaging in systematic, unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products.
- 194. The Q1 2013 Form 10-Q was accompanied by signed certifications, as required by the Sarbanes-Oxley Act of 2002, by Martin and Betterley, who certified that the Q1 2013 Form 10-Q "does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading" and "the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant."

Q. January 30, 2013 – Q2 2013 Press Release

- 195. On January 30, 2013, the Company issued a press release disclosing its second quarter 2013 financial results (the "Q2 2013 Press Release"), announcing "CSI's second-quarter revenues rose to \$25.3 million, a 28 percent gain from \$19.7 million in the second quarter of fiscal 2012."
- 196. The statements from the Q2 2013 Press Release in Paragraph 195 above were materially false and misleading when made because they did not disclose the fact that revenues from the sales of the Company's PAD Devices depended on CSI engaging in systematic, unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products.

R. <u>January 30, 2013 – Q2 2013 Earnings Call</u>

- 197. On January 30, 2013, CSI held a conference call with analysts to discuss the Company's second quarter of fiscal year 2013 earnings (the "Q2 2013 Earnings Call"). Martin and Betterley participated in this call. Betterley stated that "[f]or the second quarter of fiscal 2013 compared to a year ago, revenues grew 28% to \$25.3 million" and "[m]ore than 7,000 devices were sold in the quarter."
- 198. The statements from the Q2 2013 Earnings Call in Paragraph 197 above were materially false and misleading when made because they did not disclose the fact that revenues from the sales of the Company's PAD Devices depended on CSI engaging in systematic, unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products.

199. During the call, analysts questioned the sustainability of CSI's sales growth. Martin responded by again attributing sales growth specifically to excellent sales management, rather than illicit practices, stating:

The installation of some key management and some of the systems and programs and process that we've installed over the last six quarters continues to gain steam. The enthusiasm is high and the competence has never been as high, on the clinical and economic outcomes that we can provide, **the way we're targeting physicians** and using our valuable limited resource of time. So it has grown every quarter; the team does more and more with quality every quarter; and that's true, I think, about the company. **This was the best-managed quarter we've ever had and that is sustainable**. I think that's a great indicator that as we scale, we could handle the responsibility and continue the great results.

(Emphasis added).

200. In addition, Martin explained that among other things that Kevin Kenny has implemented, "[m]edical education has been a big hit." These statements from the Q2 2013 Earnings Call in this Paragraph and Paragraph 199 above were materially false and misleading when made because they did not disclose that CSI used illegal and unsustainable kickbacks, off-label promotions, and placing artificial orders to boost sales of the Company's PAD Devices.

S. <u>February 8, 2013 – Q2 2013 Form 10-Q</u>

201. On February 8, 2013, the Company filed its Form 10-Q Quarterly Report for the second quarter of fiscal year 2013 with the SEC (the "Q2 2013 Form 10-Q"). The Q2 2013 Form 10-Q was signed by Martin and Betterley.

202. The Q2 2013 Form 10-Q disclosed the Company's results of operations expressed as dollar amounts (in thousands) as follows:

Three Months Ended December 31,

	2012	2011
Revenues	\$ 25,309	\$ 19,718
Cost of goods sold	5,958	4,560
Gross Profit	19,351	15,158
Expenses		
Selling, general and administrative	20,418	15,733
Research and development	4,055	3,084
Total expenses	24,473	18,817
Loss from operations	(5,122)	(3,659)
Interest and other, net	(645)	(476)
Net loss and comprehensive loss	(5,767)	(4,135)

- 203. The Q2 2013 Form 10-Q then stated that the growth in revenue was "primarily from an increased number of devices sold," leaving unsaid that the sales were procured by illegal means. The statements from the Q2 2013 Form 10-Q in this Paragraph and Paragraph 202 above were materially false and misleading when made because they did not disclose the fact that revenues from the sales of the Company's PAD Devices depended on CSI engaging in systematic, unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products.
- 204. The Q2 2013 Form 10-Q was accompanied by signed certifications, as required by the Sarbanes-Oxley Act of 2002, by Martin and Betterley, who certified that the Q2 2013 Form 10-Q "does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the

circumstances under which such statements were made, not misleading" and "the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant."

T. March 20, 2013 – Prospectus

- 205. On March 20, 2013, the Company filed a prospectus, dated March 19, 2013, on a Form 424B5 with the SEC (the "March 2013 Prospectus") to announce the public offering of up to 2.3 million shares of Company common stock underwritten by Leerink Swann LLC and JMP Securities LLC. The March 2013 Prospectus incorporated a registration statement on Form S-3 filed with SEC on October 14, 2011 and declared effective on October 27, 2011. Martin and Betterley wrote, adopted, and approved of the contents of the March 2013 Prospectus.
- 206. On March 25, 2013, pursuant to the March 2013 Prospectus, the Company sold 2.3 million shares of its common stock at \$17.60 per share, yielding net proceeds to the Company, after deducting underwriting discounts, commissions, and expenses, of \$38.2 million.
- 207. In the March 2013 Prospectus, the Company represented the following regarding its billing and coding information: "In providing billing and coding information to customers, we make every effort to ensure that the billing and coding information furnished is accurate and that treating physicians understand that they are responsible for all treatment decisions."

208. The statements from the March 2013 Prospectus in Paragraph 207 above were materially false and misleading when made because CSI encouraged physicians and office staff to bill and gain reimbursement from government funded health care programs for off-label procedures and instructed which medical codes to use for such billing.

U. May 1, 2013 – Q3 2013 Press Release

- 209. On May 1, 2013, the Company issued a press release disclosing its third quarter 2013 financial results (the "Q3 2013 Press Release"), announcing "CSI's third-quarter revenues rose to \$26.5 million, a 25-percent gain from \$21.2 million in the third quarter of fiscal 2012."
- 210. The statements from the Q3 2013 Press Release in Paragraph 209 above were materially false and misleading when made because they did not disclose the fact that revenues from the sales of the Company's PAD Devices depended on CSI engaging in systematic, unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products.

V. May 1, 2013 – Q3 2013 Earnings Call

- 211. On May 1, 2013, CSI held a conference call with analysts to discuss the Company's third quarter of fiscal year 2013 earnings (the "Q3 2013 Earnings Call"). Martin and Betterley participated in this call. Betterley stated that "[f]or the third quarter of fiscal 2013 compared to a year ago, revenues grew 25% to \$26.5 million" and CSI "sold more than 7,300 devices"
- 212. The statements from the Q3 2013 Earnings Call in Paragraph 211 above were materially false and misleading when made because they did not disclose the fact

that revenues from the sales of the Company's PAD Devices depended on CSI engaging in systematic, unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products.

213. During the Q3 2013 Earnings Call, an analyst asked Martin "how do you maintain your focus on significant growth, 20%-plus, in the PAD market." In response, Martin again attributed growth to superior sales management while leaving out the reality of unethical sales tactics, stating:

You get great management. We've hired some spectacular management in every department, I mean, really across the board. One of the things that we've done with our investment opportunities is filled in that middle layer of management and that executive management with people who know what it looks like to scale and to scale of quality. I just can't say enough about the CSI team. And they're hiring phenomenal people, and the Company's backing up that hiring with employee training. Just one example is we used to struggle to afford ourselves just one national sales meeting a year during the financial crisis, and now we're committed to two, and the quality of these two, I mean, people are educated in a high-quality way, and they're really delivering that impact to their physicians, and the physicians are talking about it. There has been a substantial upgrade at the Company.

214. The statements from the Q3 2013 Earnings Call in Paragraph 213 above were materially false and misleading when made because, while touting CSI's new management, Martin did not disclose that the same management was implementing a sales strategy of illegal and improper kickbacks and off-label marketing of CSI's PAD Devices.

W. May 9, 2013 – Q3 2013 Form 10-Q

- 215. On May 9, 2013, the Company filed its Form 10-Q Quarterly Report for the third quarter of fiscal year 2013 with the SEC (the "Q3 2013 Form 10-Q"). The Q3 2013 Form 10-Q was signed by Martin and Betterley.
- 216. The Q3 2013 Form 10-Q disclosed the Company's results of operations expressed as dollar amounts (in thousands) as follows:

Three Months Ended March 31,

		- 1
	2013	2012
Revenues	\$ 26,474	21,205
Cost of goods sold	 6,241	5,132
Gross Profit	20,233	16,073
Expenses		
Selling, general and administrative	21,650	16,809
Research and development	 3,993	2,985
Total expenses	25,643	19,794
Loss from operations	(5,410)	(3,721)
Interest and other, net	(809)	(470)
Net loss and comprehensive loss	(6,219)	(4,191)

217. The Q3 2013 Form 10-Q repeated the attribution of growing revenues to "primarily [] an increased number of devices sold," while saying nothing about sales practices. The statements from the Q3 2013 Form 10-Q in this Paragraph and Paragraph 216 above were materially false and misleading when made because they did not disclose the fact that revenues from the sales of the Company's PAD Devices depended on CSI engaging in systematic, unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products.

218. The Q3 2013 Form 10-Q was accompanied by signed certifications, as required by the Sarbanes-Oxley Act of 2002, by Martin and Betterley, who certified that the Q3 2013 Form 10-Q "does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading" and "the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant."

X. <u>August 7, 2013 – Q4 2013 Press Release</u>

- 219. On August 7, 2013, the Company issued a press release disclosing its fourth quarter 2013 financial results (the "Q4 2013 Press Release"), announcing "CSI's fourth-quarter revenues rose to \$28.8 million, a 26-percent gain from \$22.9 million in the fourth quarter of fiscal 2012."
- 220. The statements from the Q4 2013 Press Release in Paragraph 219 above were materially false and misleading when made because they did not disclose the fact that revenues from the sales of the Company's PAD Devices depended on CSI engaging in systematic, unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products.

Y. <u>August 7, 2013 – Q4 2013 Earnings Call</u>

221. On August 7, 2013, CSI held a conference call with analysts to discuss the Company's fourth quarter of fiscal year 2013 earnings (the "Q4 2013 Earnings Call").

Martin and Betterley participated in this call. Betterley stated that "[f]or the fourth

quarter of fiscal 2013 compared to a year ago, revenues grew 26%, to \$28.8 million" and CSI "sold more than 8,100 devices."

222. The statements from the Q4 2013 Earnings Call in Paragraph 221 above were materially false and misleading when made because they did not disclose the fact that revenues from the sales of the Company's PAD Devices depended on CSI engaging in systematic, unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products.

Z. September 11, 2013 – Fiscal Year 2013 Annual Report

- 223. On September 11, 2013, CSI filed its Form 10-K Annual Report for the fiscal year ended June 30, 2013 with the SEC (the "2013 Form 10-K"). Betterley and Martin signed the 2013 Form 10-K.
- 224. The 2013 Form 10-K also acknowledged and discussed the applicability of the FDCA, federal Anti-Kickback Statute, and False Claims Act to the Company:

Our operations will be directly, or indirectly through our customers, subject to various state and federal fraud and abuse laws, including, without limitation, the FDCA, federal Anti-Kickback Statute and False Claims Act. These laws may impact, among other things, our proposed sales, marketing, and education programs. In addition, these laws require us to screen individuals and other companies, suppliers and vendors in order to ensure that they are not "debarred" by the federal government and therefore prohibited from doing business in the healthcare industry.

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

The federal False Claims Act prohibits persons from knowingly filing or causing to be filed a false claim to, or the knowing use of false statements to obtain payment from, the federal government. Various states have also enacted laws modeled after the federal False Claims Act.

- 225. The statements from the 2013 Form 10-K in Paragraph 224 above were materially misleading when made because they did not disclose that the Company was not in compliance with applicable laws.
- 226. The 2013 Form 10-K disclosed results of operations expressed as dollar amounts (in thousands) as follows:

Year Ended June 30,

	2013	2012
Revenues	\$ 103,897	\$ 82,490
Cost of goods sold	 24,382	19,216
Gross Profit	 79,515	63,274
Expenses:		
Selling, general and administrative	86,718	66,366
Research and development	 15,216	11,374
Total expenses	 101,934	77,740
Loss from operations	(22,419)	(14,466)
Interest and other, net	 (1,618)	(2,324)
Net loss	(24,037)	(16,790)

- 227. The statements from the 2013 Form 10-K in Paragraph 226 above were materially false and misleading when made because they did not disclose the fact that revenues from the sales of the Company's PAD Devices depended on CSI engaging in systematic, unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products.
- 228. In the 2013 Form 10-K, the Company represented the following regarding its billing and coding information: "In providing billing and coding information to customers, we make every effort to ensure that the billing and coding information furnished is accurate and that treating physicians understand that they are responsible for all treatment decisions."
- 229. The statements from the 2013 Form 10-K in Paragraph 228 above were materially false and misleading when made because CSI encouraged physicians and office staff to bill and gain reimbursement from government funded health care programs for off-label procedures and instructed which medical codes to use for such billing.
- 230. The 2013 Form 10-K was accompanied by signed certifications, as required by the Sarbanes-Oxley Act of 2002, by Martin and Betterley, who certified that the 2013 Form 10-K "does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading" and that "the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant."

AA. October 30, 2013 – Q1 2014 Press Release

- 231. On October 30, 2013, the Company issued a press release disclosing its first quarter 2014 financial results (the "Q1 2014 Press Release"), announcing "CSI's first-quarter revenues rose to \$29.8 million, a 28-percent gain from \$23.3 million in the first quarter of fiscal 2013."
- 232. The statements from the Q1 2014 Press Release in Paragraph 231 above were materially false and misleading when made because they did not disclose the fact that revenues from the sales of the Company's PAD Devices depended on CSI engaging in systematic, unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products.

BB. October 30, 2013 – Q1 2014 Earnings Call

- 233. On October 30, 2013, CSI held a conference call with analysts to discuss the Company's first quarter of fiscal year 2014 earnings (the "Q1 2014 Earnings Call"). Martin and Betterley participated in this call. Betterley stated that "[f]or the first quarter of fiscal 2014 compared to a year ago, revenues grew 28 percent to \$29.8 million" and CSI "sold more than 8,500 devices."
- 234. The statements from the Q1 2014 Earnings Call in Paragraph 233 above were materially false and misleading when made because they did not disclose the fact that revenues from the sales of the Company's PAD Devices depended on CSI engaging in systematic, unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products.

CC. November 4, 2013 – Q1 2014 Form 10-Q

- 235. On November 4, 2013, the Company filed its Form 10-Q Quarterly Report for the first quarter of fiscal year 2014 with the SEC (the "Q1 2014 Form 10-Q"). The Q1 2014 Form 10-Q was signed by Martin and Betterley.
- 236. The Q1 2014 Form 10-Q disclosed the Company's results of operations expressed as dollar amounts (in thousands) as follows:

Three Months Ended September 30,

	 2013	2012
Revenues	\$ 29,766 \$	23,293
Cost of goods sold	6,864	5,254
Gross Profit	 22,902	18,039
Expenses		
Selling, general and administrative	25,371	20,023
Research and development	 4,378	3,222
Total expenses	 29,749	23,245
Loss from operations	(6,847)	(5,206)
Interest and other, net	(445)	(4)
Net loss and comprehensive loss	(7,292)	(5,210)

- 237. The statements from the Q1 2014 Form 10-Q in Paragraph 236 above were materially false and misleading when made because they did not disclose the fact that revenues from the sales of the Company's PAD Devices depended on CSI engaging in systematic, unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products.
- 238. The Q1 2014 Form 10-Q was accompanied by signed certifications, as required by the Sarbanes-Oxley Act of 2002, by Martin and Betterley, who certified that the Q1 2014 Form 10-Q "does not contain any untrue statement of a material fact or omit

to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading" and "the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant."

DD. November 21, 2013 - Prospectus

- 239. On November 21, 2013, the Company filed a prospectus, dated November 20, 2013, on a Form 424B5 (the "November 2013 Prospectus") to announce the public offering of up to 3 million shares of Company common stock underwritten by Merrill Lynch, Pierce, Fenner & Smith, Incorporated, Leerink Swann LLC, William Blair & Company, LLC, JMP Securities LLC, Dougherty & Company LLC, Feltl and Company, Inc., and Wunderlich Securities, Inc. The November 2013 Prospectus incorporated a registration statement on Form S-3 filed with SEC on October 25, 2013 and declared effective on October 28, 2013. Martin and Betterley wrote, adopted, and approved of the contents of the November 2013 Prospectus.
- 240. On November 26, 2013, pursuant to the November 2013 Prospectus, the Company sold 3 million shares of its common stock at \$30.00 per share, yielding net proceeds to the Company, after deducting underwriting discounts, commissions, and expenses, of about \$84.4 million.
- 241. In the November 2013 Prospectus, the Company represented the following regarding its billing and coding information: "In providing billing and coding information to customers, we make every effort to ensure that the billing and coding information

furnished is accurate and that treating physicians understand that they are responsible for all treatment decisions."

242. The statements from the November 2013 Prospectus in Paragraph 241 above were materially false and misleading when made because CSI encouraged physicians and office staff to bill and gain reimbursement from government funded health care programs for off-label procedures and instructed which medical codes to use for such billing.

EE. January 29, 2014 – Q2 2014 Press Release

- 243. On January 29, 2014, the Company issued a press release disclosing its second quarter 2014 financial results (the "Q2 2014 Press Release"), announcing "CSI's second-quarter revenues rose to \$32.3 million, a 28 percent gain from \$25.3 million in the second quarter of fiscal 2013."
- 244. The statements from the Q2 2014 Press Release in Paragraph 243 above were materially false and misleading when made because they did not disclose the fact that revenues from the sales of the Company's PAD Devices depended on CSI engaging in systematic, unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products.

FF. January 29, 2014 – Q2 2014 Earnings Call

245. On January 29, 2014, CSI held a conference call with analysts to discuss the Company's second quarter of fiscal year 2014 earnings (the "Q2 2014 Earnings Call"). Martin and Betterley participated in this call. Betterley stated that "[c]ompared to

a year ago, total revenues grew 28% to \$32.3 million" and CSI "sold nearly 9,400 devices."

- 246. In his overview of the Company's quarterly results, Martin stated, "Revenues rose 28% year-over-year, and 9% sequentially over the first quarter of this fiscal year. We continue to drive success in the PAD market with our easy-to-use technology."
- 247. In response to an analyst's questions about the Company's user base and its new customer accounts, Martin stated, "We're committed to medical education and that's one of the driving forces to market expansion, which we've experienced fantastically in peripheral, we'll experience that fantastically in coronary, as well." He then specifically praised the sales team, stating "Another driver, too, Jose, is our field sales team. Their intellect and execution has been superior. They have prepared so hard in advance of handling a second franchise and it's really showing up in the quality of outcomes in the patient outcomes, but also the physician satisfaction with how we deliver that technology into an institution and get them to their first case. It's been fantastic." He repeated these statements again later, stating, "We've got a fantastic medical education capability here at the Company that we've used to drive good results, and growth and market expansion on the peripheral side."
- 248. The statements from the Q2 2014 Earnings Call in Paragraph 247 above were materially false and misleading when made because they specifically attributed "fantastic[]" sales to "easy-to-use technology," "medical education," and a well "prepared" sales team, but did not disclose the fact that revenues from the sales of the

Company's PAD Devices depended on CSI engaging in systematic, unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products.

GG. <u>February 7, 2014 – Q2 2014 Form 10-Q</u>

- 249. On February 7, 2014, the Company filed its Form 10-Q Quarterly Report for the second quarter of fiscal year 2014 with the SEC (the "Q2 2014 Form 10-Q"). The Q2 2014 Form 10-Q was signed by Martin and Betterley.
- 250. The Q2 2014 Form 10-Q disclosed the Company's results of operations expressed as dollar amounts (in thousands) as follows:

Three Months Ended December 31.

	2012	2012
	2013	2012
Revenues	\$ 32,337	\$ 25,309
Cost of goods sold	7,313	5,958
Gross Profit	25,024	19,351
Expenses		
Selling, general and administrative	27,468	20,418
Research and development	5,051	4,055
Total expenses	32,519	24,473
Loss from operations	(7,495)	(5,122)
Interest and other, net	(1,163)	(645)
Net loss and comprehensive loss	(8,658)	(5,767)

251. The statements from the Q2 2014 Form 10-Q in Paragraph 250 above were materially false and misleading when made because they did not disclose the fact that revenues from the sales of the Company's PAD Devices depended on CSI engaging in systematic, unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products.

252. The Q2 2014 Form 10-Q was accompanied by signed certifications, as required by the Sarbanes-Oxley Act of 2002, by Martin and Betterley, who certified that the Q2 2014 Form 10-Q "does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading" and "the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant."

HH. April 30, 2014 – Q3 2014 Press Release

- 253. On April 30, 2014, the Company issued a press release disclosing its third quarter 2014 financial results (the "Q3 2014 Press Release"), announcing "The company's third-quarter revenues grew to \$34.9 million, a 32 percent gain from \$26.5 million in the third quarter of fiscal 2013."
- 254. The statements from the Q3 2014 Press Release in Paragraph 253 above were materially false and misleading when made because they did not disclose the fact that revenues from the sales of the Company's PAD Devices depended on CSI engaging in systematic, unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products.

II. <u>April 30, 2014 – Q3 2014 Earnings Call</u>

255. On April 30, 2014, CSI held a conference call with analysts to discuss the Company's third quarter of fiscal year 2014 earnings (the Q3 2014 Earnings Call").

Martin and Betterley participated in this call. Betterley stated that "[c]ompared to a year ago, total revenues grew 32% to \$34.9 million" and CSI "sold nearly 10,000 devices."

- 256. The statements from the Q3 2014 Earnings Call in Paragraph 255 above were materially false and misleading when made because they did not disclose the fact that revenues from the sales of the Company's PAD Devices depended on CSI engaging in systematic, unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products.
- 257. During the Q3 2014 Earnings Call, an analyst asked Martin "how do you maintain your focus on significant growth, 20%-plus, in the PAD market." Martin replied:

You get great management. We've hired some spectacular management in every department, I mean, really across the board. One of the things that we've done with our investment opportunities is filled in that middle layer of management and that executive management with people who know what it looks like to scale and to scale of quality. I just can't say enough about the CSI team. And they're hiring phenomenal people, and the Company's backing up that hiring with employee training. Just one example is we used to struggle to afford ourselves just one national sales meeting a year during the financial crisis, and now we're committed to two, and the quality of these two, I mean, people are educated in a high-quality way, and they're really delivering that impact to their physicians, and the physicians are talking about it. There has been a substantial upgrade at the Company.

258. The statements from the Q3 2014 Earnings Call in Paragraph 257 above were materially false and misleading when made because, while touting CSI's new management, Martin did not disclose that the same management was implementing a

sales strategy of illegal and improper kickbacks and off-label marketing of CSI's PAD Devices.

JJ. May 8, 2014 – Q3 2014 Form 10-Q

- 259. On May 8, 2014, the Company filed its Form 10-Q Quarterly Report for the third quarter of fiscal year 2014 with the SEC (the "Q3 2014 Form 10-Q"). The Q3 2014 Form 10-Q was signed by Martin and Betterley.
- 260. The Q3 2014 Form 10-Q disclosed the Company's results of operations expressed as dollar amounts (in thousands) as follows:

Three Months Ended March 31,

	2014	2013
Revenues	\$ 34,945	\$ 26,474
Cost of goods sold	7,749	6,241
Gross Profit	27,196	20,233
Expenses:		
Selling, general and administrative	31,428	21,650
Research and development	5,361	3,993
Total expenses	36,789	25,643
Loss from operations	(9,593)	(5,410)
Interest and other, net	(119)	(809)
Net loss and comprehensive loss	(9,712)	(6,219)

261. The statements from the Q3 2014 Form 10-Q in Paragraph 260 above were materially false and misleading when made because they did not disclose the fact that revenues from the sales of the Company's PAD Devices depended on CSI engaging in systematic, unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products.

262. The Q3 2014 Form 10-Q was accompanied by signed certifications, as required by the Sarbanes-Oxley Act of 2002, by Martin and Betterley, who certified that the Q3 2014 Form 10-Q "does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading" and "the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant."

KK. May 9, 2014 – Notice of Department of Justice Investigation

- 263. On May 9, 2014, the Company disclosed, in a Form 8-K Current Report signed by Martin and Betterley (the "May 9, 2014 Form 8-K"), that it received notice that the DOJ was investigating the Company "to determine whether the Company has violated the False Claims Act, resulting in the submission of false claims to federal and state health care programs, including Medicare and Medicaid." The notice attached a Civil Investigative Demand ("CID") for written interrogatories and document requests that the Company was required to respond to.
- 264. In the May 9, 2014 Form 8-K, the Company continued to represent that it "maintains rigorous policies and procedures to promote compliance with the False Claims Act and other regulatory requirements, and is working with the U.S. Attorney's Office to promptly respond to the CID."
- 265. The statements from the May 9, 2014 Form 8-K in Paragraph 264 above were materially false and misleading when made because they did not disclose the fact

that CSI was engaging in systematic, unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products.

LL. <u>August 6, 2014 – Q4 2014 Press Release</u>

- 266. On August 6, 2014, the Company issued a press release disclosing its fourth quarter 2014 financial results (the "Q4 2014 Press Release"), announcing CSI "fourth-quarter revenues grew to \$39.6 million, a 37 percent gain from \$28.8 million in the fourth quarter of fiscal 2013."
- 267. The statements from the Q4 2014 Press Release in Paragraph 266 above were materially false and misleading when made because they did not disclose the fact that revenues from the sales of the Company's PAD Devices depended on CSI engaging in systematic, unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products.

MM. August 6, 2014 – Q4 2014 Earnings Call

- 268. On August 6, 2014, CSI held a conference call with analysts to discuss the Company's fourth quarter of fiscal year 2014 earnings (the "Q4 2014 Earnings Call"). Martin and Betterley participated in this call. Betterley stated that "[c]ompared to a year ago, total revenues grew 37% to \$39.6 million" and CSI "sold over 11,000 devices."
- 269. The statements from the Q4 2014 Earnings Call in Paragraph 268 above were materially false and misleading when made because they did not disclose the fact that revenues from the sales of the Company's PAD Devices depended on CSI engaging

in systematic, unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products.

NN. August 28, 2014 – Fiscal Year 2014 Annual Report

- 270. On August 28, 2014, CSI filed its Form 10-K Annual Report for the fiscal year ended June 30, 2014 with the SEC (the "2014 Form 10-K"). Betterley and Martin signed the 2014 Form 10-K.
- 271. The 2014 Form 10-K also acknowledged and discussed the applicability of the FDCA, federal Anti-Kickback Statute, and False Claims Act to the Company:

Our operations will be directly, or indirectly through our customers, subject to various state and federal fraud and abuse laws, including, without limitation, the FDCA, federal Anti-Kickback Statute and False Claims Act. These laws may impact, among other things, our proposed sales, marketing, and education programs. In addition, these laws require us to screen individuals and other companies, suppliers and vendors in order to ensure that they are not "debarred" by the federal government and therefore prohibited from doing business in the healthcare industry.

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of

patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

The federal False Claims Act prohibits persons from knowingly filing or causing to be filed a false claim to, or the knowing use of false statements to obtain payment from, the federal government. Various states have also enacted laws modeled after the federal False Claims Act.

- 272. In addition to the above, the 10-K also stated, in a paragraph discussing the Department of Justice investigation into its sales practices, that "[w]e maintain rigorous policies and procedures to promote compliance with the False Claims Act and other regulatory requirements."
- 273. The statements from the 2014 Form 10-K in Paragraph 272 above were materially misleading when made because they did not disclose that the Company was not in compliance with applicable laws.
- 274. The 2014 Form 10-K disclosed results of operations expressed as dollar amounts (in thousands) as follows:

Year Ended June 30,

	2014	2013	
Revenues	\$ 136,612	\$ 103,897	
Cost of goods sold	31,041	24,382	
Gross profit	105,571	79,515	
Gross margin	77.3%	76.5%	
Expenses:			
Selling, general and administrative	117,994	86,718	
Research and development	21,066	15,216	
Total expenses	139,060	101,934	
Loss from operations	(33,489)	(22,419)	
Interest and other, net	(1,801)	(1,618)	
Net loss	(35,290)	(24,037)	

- 275. The statements from the 2014 Form 10-K in Paragraph 274 above were materially false and misleading when made because they did not disclose the fact that revenues from the sales of the Company's PAD Devices depended on CSI engaging in systematic, unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products.
- 276. In the 2014 Form 10-K, the Company represented the following regarding its billing and coding information: "In providing billing and coding information to customers, we make every effort to ensure that the billing and coding information furnished is accurate and that treating physicians understand that they are responsible for all treatment decisions."
- 277. The statements from the 2014 Form 10-K in Paragraph 276 above were materially false and misleading when made because CSI encouraged physicians and office staff to bill and gain reimbursement from government funded health care programs for off-label procedures and instructed which medical codes to use for such billing.
- 278. The 2014 Form 10-K was accompanied by signed certifications, as required by the Sarbanes-Oxley Act of 2002, by Martin and Betterley, who certified that the 2014 Form 10-K "does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading" and that "the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant."

OO. October 29, 2014 – Q1 2015 Press Release

- 279. On October 29, 2014, the Company issued a press release disclosing its first quarter 2015 financial results (the "Q1 2015 Press Release"), stating that CSI's "first-quarter revenues increased 39 percent to \$41.4 million, from \$29.8 million in the first quarter of fiscal 2014."
- 280. The statements from the Q1 2015 Press Release in Paragraph 279 above were materially false and misleading when made because they did not disclose the fact that revenues from the sales of the Company's PAD Devices depended on CSI engaging in systematic, unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products.
- 281. The 1Q 2015 Press Release included a statement by Martin regarding the reason for the Company's sales growth:

Our robust sales growth is driven by market expansion for treatment of both peripheral and coronary artery disease, as a growing number of physicians embrace our technology to solve their most difficult interventional vascular challenges—specifically calcified lesions. Treating these patients has historically led to higher rates of adverse events and retreatment, resulting in higher costs.

282. The statements from the Q1 2015 Press Release in Paragraph 281 above were materially false and misleading when made because Martin did not disclose that the reason for the Company's robust sales growth was because CSI was engaging in systematic, unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products."

- 283. This was the Company's first quarter following the disclosure of the Department of Justice investigation and as part of the 1Q 2015 Press Release, Martin highlighted a new initiative to "optimiz[e] [its] sales force."
- 284. The statements from the Q1 2015 Press Release in Paragraph 283 above were materially false and misleading when made because Martin did not disclose that the Company's sales force optimization plan involved ceasing the prior sales practices of illegal kickbacks and off-label marketing of its PAD Devices that CSI relied on for its sales revenue.
- 285. The effect of CSI's illegal conduct on its share price is made clear by the increase in expenses and sharp decline in revenues the Company experienced after the sales force optimization. It was unknown to investors at the time of the announcement, but without the advantage of kickbacks and improper off-label promotions, CSI's financial results would consistently disappoint throughout the remainder of the Class Period, leading to significant damage to the Class.

PP. October 29, 2014 – Q1 2015 Earnings Call

- 286. On October 29, 2014, CSI held a conference call with analysts to discuss the Company's first quarter of fiscal year 2015 earnings (the "Q1 2015 Earnings Call"). Martin and Betterley participated in this call. Betterley stated that "[c]ompared to a year ago, total revenues grew 39% to \$41.4 million" and CSI "sold over 11,500 devices."
- 287. The statements from the Q1 2015 Earnings Call in Paragraph 286 above were materially false and misleading when made because they did not disclose the fact that revenues from the sales of the Company's PAD Devices depended on CSI engaging

in systematic, unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products.

- 288. On the Q1 2015 Earnings Call, Martin and Betterley explained the Company's sales force "optimization" efforts include the expansion of the Company's sales force and the provision of new training to its members, including cross-training for sales of multiple types of Company products. Moreover, in response to an analyst's question on how the Company was growing accounts so fast over the previous several quarters, and whether the quality of sales people had anything to do with it, Betterley stated, "Yes, it's more people, but I think also with the growing office-based labs that has added to the quarter as well . . ."
- 289. By specifically attributing growing accounts to the quality of sales people, as well as the increasing number of OBLs, while neglecting to mention that the sales force was employing unethical sales tactics and that the Company was actively helping the creation of additional OBLs, these statements were materially false and misleading when made. Moreover, Martin and Betterley did not disclose that the Company's sales force "optimization" plan involved ceasing the prior sales practices of illegal kickbacks and off-label marketing of its PAD Devices that CSI relied on for its sales revenue.

QQ. November 7, 2014 – Q1 2015 Form 10-Q

290. On November 7, 2014, the Company filed its Form 10-Q Quarterly Report for the first quarter of fiscal year 2015 with the SEC (the "Q1 2015 Form 10-Q"). The Q1 2015 Form 10-Q was signed by Martin and Betterley.

291. The Q1 2015 Form 10-Q disclosed the Company's results of operations expressed as dollar amounts (in thousands) as follows:

Three Months Ended September 30,

		2014	2013	
Revenues	\$	41,354 \$	29,766	
Cost of goods sold		8,885	6,864	
Gross Profit		32,469	22,902	
Expenses				
Selling, general and administrative		33,507	25,371	
Research and development	<u> </u>	7,152	4,378	
Total expenses		40,659	29,749	
Loss from operations		(8,190)	(6,847)	
Interest and other, net		(34)	(445)	
Net loss and comprehensive loss		(8,224)	(7,292)	

- 292. The statements from the Q1 2015 Form 10-Q in Paragraph 291 above were materially false and misleading when made because they did not disclose the fact that revenues from the sales of the Company's PAD Devices depended on CSI engaging in systematic, unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products.
- 293. The Q1 2015 Form 10-Q was accompanied by signed certifications, as required by the Sarbanes-Oxley Act of 2002, by Martin and Betterley, who certified that the Q1 2015 Form 10-Q "does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading" and "the financial statements, and other financial information included in this report, fairly present

in all material respects the financial condition, results of operations and cash flows of the registrant."

RR. <u>January 28, 2015 – Q2 2015 Press Release</u>

- 294. On January 28, 2015, the Company issued a press release disclosing its second quarter 2014 financial results (the "Q2 2015 Press Release"), announcing CSI's "second-quarter revenues increased 38 percent to \$44.7 million, from \$32.3 million in the second quarter of fiscal 2014."
- 295. The statements from the Q2 2015 Press Release in Paragraph 294 above were materially false and misleading when made because they did not disclose the fact that revenues from the sales of the Company's PAD Devices depended on CSI engaging in systematic, unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products.

SS. <u>January 29, 2015 – Q2 2015 Earnings Call</u>

- 296. On January 29, 2015, CSI held a conference call with analysts to discuss the Company's second quarter of fiscal year 2015 earnings (the "Q2 2015 Earnings Call"). Martin and Betterley participated in this call. Betterley stated that "[c]ompared to last year's second quarter total revenues grew 38% to \$44.7 million" and CSI "sold nearly 13,000 devices."
- 297. The statements from the Q2 2015 Earnings Call in Paragraph 296 above were materially false and misleading when made because they did not disclose the fact that revenues from the sales of the Company's PAD Devices depended on CSI engaging

in systematic, unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products.

- 298. On the Q2 2015 Earnings Call, Martin stated that the Company "expanded our sales force."
- 299. The statements from the Q2 2015 Earnings Call in Paragraph 298 above were materially false and misleading when made because Martin did not disclose the fact that the sales force expansion was required because the Company ceased the prior sales practices of illegal kickbacks and off-label marketing of its PAD Devices that CSI relied on for its sales revenue.

TT. February 6, 2015 – Q2 2015 Form 10-Q

- 300. On February 6, 2015, the Company filed its Form 10-Q Quarterly Report for the second quarter of fiscal year 2015 with the SEC (the "Q2 2015 Form 10-Q"). The Q2 2015 Form 10-Q was signed by Martin and Betterley.
- 301. The Q2 2015 Form 10-Q disclosed the Company's results of operations expressed as dollar amounts (in thousands) as follows:

Three Months Ended December 31,

	2014	2013
Revenues	\$ 44,732 \$	32,337
Cost of goods sold	 9,346	7,313
Gross Profit	35,386	25,024
Expenses	·	
Selling, general and administrative	32,553	27,468
Research and development	8,085	5,051
Total expenses	 40,638	32,519
Loss from operations	(5,252)	(7,495)
Interest and other, net	 (21)	(1,163)
Net and comprehensive loss	(5,273)	(8,658)

- 302. The statements from the Q2 2015 Form 10-Q in Paragraph 301 above were materially false and misleading when made because they did not disclose the fact that the increased expenses for the sales force optimization plan was required because the Company ceased the prior sales practices of illegal kickbacks and off-label marketing of its PAD Devices that CSI relied on for its sales revenue.
- 303. The Q2 2015 Form 10-Q was accompanied by signed certifications, as required by the Sarbanes-Oxley Act of 2002, by Martin and Betterley, who certified that the Q2 2015 Form 10-Q "does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading" and "the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant."

UU. April 29, 2015 – Q3 2015 Press Release

- 304. On April 29, 2015, the Company issued a press release disclosing its third quarter 2015 financial results (the "3Q 2015 Press Release").
- 305. The 3Q 2015 Press Release reported significant losses for the Company, due, in part, to "sales force expansion." Specifically, the Company reported the following figures:

CSI's fiscal 2015 third-quarter net loss was \$(10.7) million, or \$(0.34) per common share, compared to a net loss of \$(9.7) million, or \$(0.32) per common share, in the fiscal 2014 third quarter. Net loss increased from the prior year primarily due to planned investments, including sales force expansion and coronary product commercialization.

306. The statements from the Q3 2015 Press Release in Paragraph 305 above were materially false and misleading when made because they did not disclose the fact that the increased expenses for the sales force optimization plan was required because the Company ceased the prior sales practices of illegal kickbacks and off-label marketing of its PAD Devices that CSI relied on for its sales revenue.

VV. April 29, 2015 – Q3 2015 Earnings Call

307. On April 29, 2015, CSI held a conference call with analysts to discuss the Company's third quarter of fiscal year 2015 earnings (the "Q3 2015 Earnings Call"). Martin and Betterley participated in this call. Betterley stated that "[c]ompared to last year's third quarter, total revenues grew 35% to \$47 million" and CSI "sold over 13,000 devices."

- 308. The statements from the Q3 2015 Earnings Call in Paragraph 307 above were materially false and misleading when made because they did not disclose the fact that revenues from the sales of the Company's PAD Devices depended on CSI engaging in systematic, unsustainable violations of medical device marketing laws and regulations and placing artificial orders to boost the sales of the Company's products.
- 309. On the Q3 2015 Earnings Call, Martin stated that the Company's plan to "expand[] the sales force . . . from 160 members [to] 250," and that the reason for this sales force expansion was because "there are so many patients in need with coronary calcium or peripheral calcium . . . We can't we literally can't get to all those patients and we've, one, expanded the sales force . . . In addition, we're going to train each one of those to handle both franchises."
- 310. The statements from the Q3 2015 Earnings Call in Paragraph 309 above were materially false and misleading when made because Martin did not disclose the fact that the sales force expansion was required because the Company ceased the prior sales practices of illegal kickbacks and off-label marketing of its PAD Devices that CSI relied on for its sales revenue.

WW. May 8, 2015 – Q3 2015 Form 10-Q

- 311. On May 8, 2015, the Company filed its Form 10-Q Quarterly Report for the third quarter of fiscal year 2015 with the SEC (the "Q3 2015 Form 10-Q"). The Q3 2015 Form 10-Q was signed by Martin and Betterley.
- 312. The Q3 2015 Form 10-Q disclosed the Company's results of operations expressed as dollar amounts (in thousands) as follows:

Three Months Ended March 31,

	2015	2014
Revenues	\$ 47,004 \$	34,945
Cost of goods sold	10,416	7,749
Gross Profit	 36,588	27,196
Expenses:		
Selling, general and administrative	39,354	31,428
Research and development	7,777	5,361
Total expenses	 47,131	36,789
Loss from operations	(10,543)	(9,593)
Interest and other, net	 (113)	(119)
Net loss	(10,656)	(9,712)

- 313. The statements from the Q3 2015 Form 10-Q in Paragraph 312 above were materially false and misleading when made because they did not disclose that the increased expenses from the Company's expansion of its sales and marketing organization was necessary to maintain sales of its PAD Devices after the Company ceased the prior sales practices of illegal kickbacks and off-label marketing of its PAD Devices that CSI relied on for its sales revenue.
- 314. The Q3 2015 Form 10-Q was accompanied by signed certifications, as required by the Sarbanes-Oxley Act of 2002, by Martin and Betterley, who certified that the Q3 2015 Form 10-Q "does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading" and "the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant."

XX. August 5, 2015 – 4Q 2015 Press Release

- 315. On August 5, 2015, the Company issued a press release disclosing its fourth quarter 2015 financial results (the "4Q 2015 Press Release").
- 316. The 4Q 2015 Press Release reported significant losses again for the Company. Specifically, the Company reported the following figures for the fourth quarter 2015:

Net loss was \$(8.7) million, or \$(0.27) per common share, compared to a net loss of \$(9.6) million, or \$(0.31) per common share, in the fiscal 2014 fourth quarter. Adjusted EBITDA loss improved to \$(4.1) million compared to \$(5.9) million a year earlier.

- 317. The statements from the Q4 2015 Form 10-Q in Paragraph 316 above were materially false and misleading when made because they did not disclose that the net losses stemming from the Company's expansion of its sales and marketing organization was necessary to maintain sales of its PAD Devices after the Company ceased the prior sales practices of illegal kickbacks and off-label marketing of its PAD Devices that CSI relied on for its sales revenue.
- 318. The 4Q 2015 Press Release listed the Company's unaudited consolidated statements of operations showing that the primary reason for the net loss was the Company's \$38.3 million in selling, general and administrative expenses for the fourth quarter of fiscal year 2015.
- 319. The statements from the Q4 2015 Form 10-Q in Paragraph 318 above were materially false and misleading when made because they did not disclose that the increase to the Company's selling, general, and administrative expenses was necessary to

maintain sales of its PAD Devices after the Company ceased the prior sales practices of illegal kickbacks and off-label marketing of its PAD Devices that CSI relied on for its sales revenue.

320. The Company attributed the losses, in part, to the Company's "sales force expansion" strategy, which fell short of targets. The 4Q 2015 Press Release, quoting Martin, stated the following regarding the Company's sales force optimization and its shortcomings:

Significant progress continued on our sales optimization plan in the fourth quarter. Cross training of our sales force to sell both peripheral and coronary products advanced with over 140 representatives now trained. Productivity goals were also achieved per representative, further validating that our dual application sales approach will provide attractive growth and lead to profitability in the future. The related sales force expansion, however, fell short of our targets, resulting in an average of approximately 9 open positions during the quarter. As a consequence, revenue was slightly below our expectations. We have taken actions to reach our planned sales force level by the end of the fiscal 2016 first quarter and beyond.

321. The statements from the Q4 2015 Form 10-Q in Paragraph 320 above were materially false and misleading when made because they did not disclose that the sales force optimization plan was necessary to maintain sales of its PAD Devices after the Company ceased the prior sales practices of illegal kickbacks and off-label marketing of its PAD Devices that CSI relied on for its sales revenue.

YY. August 27, 2015 – Fiscal Year 2015 Annual Report

- 322. On August 27, 2015, CSI filed its Form 10-K Annual Report for the fiscal year ended June 30, 2015 with the SEC (the "2015 Form 10-K"). Betterley and Martin signed the 2015 Form 10-K.
- 323. The 2015 Form 10-K also acknowledged and discussed the applicability of the FDCA, federal Anti-Kickback Statute, and False Claims Act to the Company:

Our operations are directly, or indirectly through our customers, subject to various state and federal fraud and abuse laws, including, without limitation, the FDCA, federal Anti-Kickback Statute and False Claims Act. These laws may impact, among other things, our proposed sales, marketing, and education and clinical programs. In addition, these laws require us to screen individuals and other companies, suppliers and vendors in order to ensure that they are not "debarred" by the federal government and therefore prohibited from doing business in the healthcare industry.

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

The federal False Claims Act prohibits persons from knowingly filing or causing to be filed a false claim to, or the knowing use of false statements to obtain payment from, the federal government. Various states have also enacted laws modeled after the federal False Claims Act.

- 324. In addition to the above, the 10-K also stated, in a paragraph discussing the Department of Justice investigation into its sales practices, that "[w]e maintain rigorous policies and procedures to promote compliance with the False Claims Act and other regulatory requirements."
- 325. The statements from the 2015 Form 10-K in Paragraph 324 above were materially misleading when made because they did not disclose that the Company was not in compliance with applicable laws.
- 326. The 2015 Form 10-K disclosed results of operations expressed as dollar amounts (in thousands) as follows:

Year Ended June 30,

	2015	2014
Revenues	\$ 181,544	\$ 136,612
Cost of goods sold	39,520	31,041
Gross profit	142,024	105,571
Gross margin	78.2%	77.3%
Expenses:		
Selling, general and administrative	143,684	117,994
Research and development	30,977	21,066
Total expenses	174,661	139,060
Loss from operations	(32,637)	(33,489)
Interest and other, net	(185)	(1,801)
Net loss	(32,822)	(35,290)

327. The statements from the 2015 Form 10-K in Paragraph 326 above were materially false and misleading when made because they did not disclose that the

increased expenses from the Company's expansion of its sales and marketing organization was necessary to maintain sales of its PAD Devices after the Company ceased the prior sales practices of illegal kickbacks and off-label marketing of its PAD Devices that CSI relied on for its sales revenue.

- 328. In the 2015 Form 10-K, the Company represented the following regarding its billing and coding information: "In providing billing and coding information to customers, we make every effort to ensure that the billing and coding information furnished is accurate and that treating physicians understand that they are responsible for all treatment decisions."
- 329. The statements from the 2015 Form 10-K in Paragraph 328 above were materially false and misleading when made because CSI encouraged physicians and office staff to bill and gain reimbursement from government funded health care programs for off-label procedures and instructed which medical codes to use for such billing.
- 330. The 2015 Form 10-K was accompanied by signed certifications, as required by the Sarbanes-Oxley Act of 2002, by Martin and Betterley, who certified that the 2014 Form 10-K "does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading" and that "the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant."

ZZ. October 7, 2015 – Q1 2016 Press Release

- 331. On October 7, 2015, the Company issued a press release announcing preliminary first quarter financial results for the 2016 fiscal year for the Company (the "1Q 2016 Press Release").
- 332. This was the first earnings quarter after *qui tam* action was unsealed and the 1Q 2016 Press Release revealed that revenue fell from \$48.5 million the prior quarter to \$43.9 million in the first quarter of 2016.
- 333. The 1Q 2016 Press Release again reported significant losses again for the Company. Specifically, the Company reported the following figures for the first quarter 2016:

The fiscal 2016 first quarter net loss is anticipated to be in the range of \$(13.1) million to \$(13.9) million, or \$(0.41) to \$(0.43) per common share, compared to a net loss of \$(8.2) million, or \$(0.26) per common share, in the fiscal 2015 first quarter.

- 334. The statements from the 1Q 2016 Press Release in Paragraph 333 above were materially false and misleading when made because they did not disclose that the net losses stemming from the Company's expansion of its sales and marketing organization was necessary to maintain sales of its PAD Devices after the Company ceased the prior sales practices of illegal kickbacks and off-label marketing of its PAD Devices that CSI relied on for its sales revenue.
- 335. The 1Q 2016 Press Release, quoting Martin, stated the following about the Company's sales force optimization:

We continued to make progress on our sales optimization strategy to significantly expand our sales organization, while cross training representatives to sell both peripheral and coronary applications. However, as our recent results suggest, some aspects of the transition have been challenging. After a thorough review, we believe we have taken the right steps to address the immediate challenges and continue to expect the vast majority of the optimization effort to be completed by the third quarter of this fiscal year. We see no change in our multi-billion market opportunity, or our potential to address it. Our unique orbital atherectomy technology is groundbreaking, addressing the population of underserved patients with calcified artery We believe our sales optimization strategy, including a large focused sales force, is the ideal approach to capitalize on this opportunity and drive attractive double digit revenue growth and profitability in the future.

336. The statements from the 1Q 2016 Press Release in Paragraph 335 above were materially false and misleading when made because they did not disclose that the Company's sales force optimization involved ceasing the prior sales practices of illegal kickbacks and off-label marketing of its PAD Devices that CSI relied on for its sales revenue.

AAA. November 4, 2015 - Q1 2016 Earnings Call

- 337. On November 4, 2015, CSI held a conference call with analysts to discuss the Company's first quarter of fiscal year 2016 earnings (the "Q1 2016 Earnings Call"). Martin and Betterley participated in this call. Betterley stated that "[o]perating expenses rose 19% over last year, primarily from planned investments related to sales force optimization and expansion."
- 338. In direct response to an analyst's questions about the sales force "disruption" and "turnover," Martin stated:

First, our communication is intensified with really key audiences -- our sales management team, our faculty, our field sales trainers, our overall sales teams. So we've increased communication. We've got something great to offer -- some small territories, no travel, the ability to get intimate with customers in your home town and make home-town heroes. It's a great story that might have been lost last year in some aggressive quota setting and the related compensation divot for some of our sales people. We have addressed that since October 1. Morale is high. . . . So yes, things are on the move and we're feeling great about it.

339. The statements from the Q1 2016 Earnings Call in Paragraph 338 above were materially false and misleading when made because the Company did not disclose the fact that the sales force expansion was required because the Company ceased the prior sales practices of illegal kickbacks and off-label marketing of its PAD Devices that CSI relied on for its sales revenue.

BBB. November 6, 2015 – 1Q 2016 Form 10-Q

- 340. On November 6, 2015, the Company filed its Form 10-Q Quarterly Report for the first quarter of fiscal year 2016 with the SEC (the "Q1 2016 Form 10-Q"). The Q1 2016 Form 10-Q was signed by Martin and Betterley.
- 341. The Q1 2016 Form 10-Q disclosed the Company's results of operations expressed as dollar amounts (in thousands) as follows:

Three Months Ended September 30,

	2015	2014
Revenues	\$ 43,871	\$ 41,354
Cost of goods sold	8,771	8,885
Gross Profit	35,100	32,469
Expenses		
Selling, general and administrative	41,395	33,507
Research and development	6,941	7,152
Total expenses	48,336	40,659
Loss from operations	(13,236)	(8,190)
Interest and other, net	(25)	(34)
Net loss	(13,261)	(8,224)

- 342. The statements from the Q1 2016 Form 10-Q in Paragraph 341 above were materially false and misleading when made because they did not disclose that the increased expenses from the Company's expansion of its sales and marketing organization was necessary to maintain sales of its PAD Devices after the Company ceased the prior sales practices of illegal kickbacks and off-label marketing of its PAD Devices that CSI relied on for its sales revenue.
- 343. The Q1 2016 Form 10-Q was accompanied by signed certifications, as required by the Sarbanes-Oxley Act of 2002, by Martin and Betterley, who certified that the Q1 2016 Form 10-Q "does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading" and "the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant."

CCC. January 21, 2016 – Q2 2016 Press Release and Earnings Call

- 344. On January 21, 2016, the Company issued a press release disclosing its second quarter fiscal 2016 financial results (the "Q2 2016 Press Release").
- 345. The Q2 2016 Press Release again reported significant losses for the Company. Specifically, the Company reported the following figures for the first quarter 2016:

Net loss was \$(15.2) million, or \$(0.47) per common share, compared to a net loss of \$(5.3) million, or \$(0.17) per common share, in the fiscal 2015 second quarter. Adjusted EBITDA loss was \$(11.1) million versus \$(1.3) million a year earlier.

- 346. The statements from the Q2 2016 Press Release in Paragraph 345 above were materially false and misleading when made because they did not disclose that the net losses stemming from the Company's expansion of its sales and marketing organization was necessary to maintain sales of its PAD Devices after the Company ceased the prior sales practices of illegal kickbacks and off-label marketing of its PAD Devices that CSI relied on for its sales revenue.
- 347. The Q2 2016 Press Release reported revenue of only \$41.4 million, below the Company's prior revenue guidance of between \$42.5 million and \$44.0 million. The Company attributed the guidance miss to the "continued effects of the sales force transition."
- 348. The statements from the Q2 2016 Press Release in Paragraph 347 above were materially false and misleading when made because they did not disclose that the increased expenses from the Company's expansion of its sales and marketing

organization was necessary to maintain sales of its PAD Devices after the Company ceased the prior sales practices of illegal kickbacks and off-label marketing of its PAD Devices that CSI relied on for its sales revenue.

349. Addressing the Company's first quarter fiscal 2016 financial results, Scott Ward, the Company's Chairman and Interim Chief Executive Officer,⁸ stated in relevant part:

CSI's sales force expansion and implementation of a dual franchise model, selling both coronary and peripheral applications, has been challenging and is affecting our near term sales performance. We have gained meaningful insights during the transition and we are encouraged by recent progress. The sales organization continues to gain valuable experience and we have begun to adjust our sales model at the local level, adopting a more flexible approach where warranted.

- 350. During a conference call with analysts on the same day, Ward again attributed the sales force disruption to a change to a dual-franchise strategy, stating, "[t]he rapid expansion of our sales force and the implementation of a dual franchise strategy has been a major undertaking, and the related disruption has negatively affected our sales performance."
- 351. The statements from the Q2 2016 Press Release in Paragraph 350 above were materially false and misleading when made because they did not disclose that the Company's expansion of its sales and marketing organization was necessary to maintain sales of its PAD Devices after the Company ceased the prior sales practices of illegal

⁸ Scott Ward was appointed Interim Chief Executive Officer effective December 1, 2015 as a result of Martin taking a medical leave of absence.

kickbacks and off-label marketing of its PAD Devices that CSI relied on for its sales revenue.

352. Benchmark analysts reported skepticism on the Company's ability to turnaround its revenue losses, stating in a January 22, 2016 report, "[t]he company's past predictions have not been accurate, and at this point it may be better to wait until success is demonstrated before stepping in or adding to positions."

DDD. Defendants' Wrongful Conduct

- 353. Each of the statements by CSI referenced above, was materially incomplete, false and misleading as to the Company's business, operations, and prospects.
- 354. Specifically, Defendants knowingly or recklessly made and/or caused to be made materially incomplete, false and misleading statements of fact by leading the investing public to believe that the Company complied with applicable laws and regulations governing the marketing and sale of its PAD Devices and failing to disclose that (1) the Company was engaged in illegal and improper off-label marketing of its PAD Devices, (2) the Company relied upon illegal kickbacks to promote its PAD Devices to medical practitioners, (3) the Company relied on such illegal and improper measures to drive sales of its PAD Devices, and (4) the Company's unlawful sales tactics forced the Company to initiate a retraining program that cost the Company millions of dollars and led to multiple negative earnings periods. These facts pertained to the Company's business, operations, and prospects and were known to Martin and Betterley or recklessly disregarded by them. Martin and Betterley knowingly or recklessly made and/or caused

to be made materially incomplete, false and misleading statements of fact and failed to correct and/or caused the Company to fail to correct the false and/or misleading statements and/or omissions of material fact referenced.

X. <u>CLASS ACTION ALLEGATIONS</u>

- 355. Lead Plaintiffs bring this action as a class action pursuant to Federal Rules of Civil Procedure 23(a) and 23(b)(3), on behalf of a Class consisting of all persons and entities that purchased or otherwise acquired CSI common stock during the Class Period. Excluded from the Class are: (i) Defendants; (ii) members of the immediate family of any Defendant who is an individual; (iii) any person who was an officer or director of CSI during the Class Period; (iv) any firm, trust, corporation or other entity in which any Defendant has or had a controlling interest; (v) CSI's employee retirement and benefit plan(s); and (vi) the legal representatives, affiliates, heirs, successors-in-interest, or assigns of any such excluded person.
- 356. The members of the Class are so numerous that joinder of all members is impracticable. According to the Company's Fiscal Year 2015 Form 10-K Annual Report, filed with the SEC on August 27, 2015, CSI had more than 32 million shares of stock outstanding that actively traded on NASDAQ. While the exact number of Class members is unknown to Lead Plaintiffs at this time and can only be ascertained through appropriate discovery, Lead Plaintiffs believe that there are thousands of members of the proposed Class. Record owners and other members of the Class may be identified from records maintained by CSI or its transfer agent and may be notified of the pendency of this action

by mail, using the form of notice similar to that customarily used in securities class actions.

- 357. Lead Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of the federal securities laws.
- 358. Lead Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation.
- 359. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class.

 Among the questions of law and fact common to the Class are:
- (a) whether the federal securities laws were violated by Defendants' acts and omission as alleged herein;
- (b) whether statements made (or omissions) by Defendants to the investing public during the Class Period misrepresented (or omitted) to state material facts about CSI's business, in particular the Company's reliance upon illegal kickbacks, improper off-label promotions, and other violations of applicable laws and regulations to drive sales of its products, as well as the Company's operations and management;
- (c) whether the Defendants made their misstatements or misrepresentations with the requisite scienter; and
- (d) the extent to which the members of the Class have sustained damages and the proper measure of damages.

360. A class action is superior to other available methods for the fair and efficient adjudication of this controversy because, among other things, joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

XI. ADDITIONAL CONTROL PERSON ALLEGATIONS

- 361. Martin and Betterley, because of their positions of control and authority as senior executive officers, had access to the adverse, undisclosed information about CSI's business and operations through their access to internal corporate documents and information, conversations and associations with other corporate officers and employees, attendance at management and Board of Directors meetings and committees thereof, and reports and other information provided to them in connection therewith.
- 362. Martin and Betterley, by virtue of their high-level positions with the Company, directly participated in the management of the Company, and were directly involved in the day-to-day operations of the Company at the highest levels. Martin and Betterley participated in drafting, preparing, and/or approving the public statements and communications complained of herein and were aware of, or recklessly disregarded, the material misstatements contained therein and omissions therefrom, and were aware of its materially false and misleading nature.
- 363. Martin and Betterley, as senior executive officers of the Company, were able to and did control the content of the various SEC filings, press releases, and other

public statements pertaining to the Company during the Class Period. Martin and Betterley were provided with copies of the documents and statements alleged herein to be materially false and misleading prior to or shortly after their issuance or had the ability and opportunity to prevent their issuance or cause them to be corrected. Accordingly, Martin and Betterley are responsible for the accuracy of the public reports, releases, and other statements detailed herein and are primarily liable for the misrepresentations and omissions contained therein.

- 364. As senior officers and controlling persons of a publicly-held company whose securities were, during the relevant time, registered with the SEC pursuant to the Exchange Act and traded on the NASDAQ, Martin and Betterley had a duty to promptly disseminate accurate and truthful information with respect to the Company's operations and business, and to correct any previously issued statements that were or had become materially misleading or untrue, so that the market price of the Company's publicly-traded securities would be based upon truthful and accurate information. Martin's and Betterley's wrongdoing during the Class Period violated these specific requirements and obligations.
- 365. Betterley is liable as a primary participant in a wrongful course of conduct that operated as a fraud and deceit on purchasers of CSI's common stock during the Class Period, which included the dissemination of materially false and misleading statements (both affirmative statements and statements rendered misleading because of material omissions) regarding the Company's business and operations during the Class Period.

 The course of conduct: (i) deceived the investing public regarding CSI's operations and

business, specifically that the Company relied upon illegal kickbacks, improper off-label promotions, and other violations of applicable laws and regulations in order to drive sales of its product, and the true value of CSI's securities; and (ii) caused Lead Plaintiffs and other members of the Class to purchase CSI's securities at artificially inflated prices, which fell as the truth about CSI's business practices ultimately became known.

366. In making the statements complained of herein, Martin and Betterley, who were senior officers and controlling persons of CSI, were acting on behalf of the Company in the regular course of business. Therefore, each of the statements made by Martin and Betterley is attributable to the Company.

XII. APPLICABILITY OF PRESUMPTION OF RELIANCE UNDER THE AFFILIATED *UTE* DOCTRINE, AND/OR, IN THE ALTERNATIVE, THE FRAUD ON THE MARKET DOCTRINE

- 367. Lead Plaintiffs are entitled to a presumption of reliance under *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the claims asserted herein are predicated in part upon omissions of material fact which there was a duty to disclose.
- 368. Lead Plaintiffs are entitled to a presumption of reliance because, as more fully alleged above, the Defendants failed to disclose material information regarding their reliance on illegal kickbacks, improper off-label promotions, and other violations of applicable laws and regulations during the Class Period.
- 369. Alternatively, Lead Plaintiffs are entitled to a presumption of reliance under the fraud on the market doctrine because at all relevant times, the market for CSI's securities was an efficient market for the following reasons, among others:

- (a) CSI's stock met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;
- (b) As a regulated issuer, CSI filed periodic public reports with the SEC (and was eligible to file SEC Form S-1) and the NASDAQ;
- c) CSI regularly communicated with public investors through established market communication mechanisms, including regular disseminations of press releases on the national circuits of major newswire services and other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and
- (d) CSI was followed by numerous investor research services that published publicly available reports, as well as by several securities analysts at major brokerage firms who wrote reports that were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.
- 370. As a result of the foregoing, the market for CSI's securities promptly digested current information regarding CSI from all publicly available sources and reflected such information in CSI's stock price. Under these circumstances, all purchasers of CSI's securities during the Class Period suffered similar injury through their purchase of CSI's securities at artificially inflated prices and a presumption of reliance applies.

XIII. INAPPLICABILITY OF STATUTORY SAFE HARBOR

- 371. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements or omissions pleaded in this Complaint. Many of the specific statements pleaded herein were not identified as "forward-looking statements" when made. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Further, most of the identified false and misleading statements and omissions herein are not forward looking statements, but are statements of current and historic fact regarding CSI's practices.
- 372. To the extent that any of the false and misleading statements identified herein are mixed statements of current fact and forward looking projection, the portion of those statements relating to current fact are not protected by the safe harbor. This includes, but is not necessarily limited to, the statements contained in ¶¶ 134-352.
- 373. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of CSI who knew that those statements were false when made.

XIV. CAUSES OF ACTION

COUNT I

Violation Of Section 10(b) Of The Exchange Act And Rule 10b-5(b) <u>Promulgated Thereunder Against All Defendants</u>

- 374. Lead Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.
- 375. During the Class Period, CSI, Martin and Betterley carried out a course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Lead Plaintiffs and other Class members, as alleged herein; and (ii) cause Lead Plaintiffs and other members of the Class to purchase CSI securities at artificially inflated prices. In furtherance of this unlawful course of conduct, these Defendants, and each of them, took the actions set forth herein.
- 376. CSI, Martin and Betterley: (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for CSI common stock in violation of Section 10(b) of the Exchange Act and Rule 10b-5. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons.
- 377. Martin and Betterley, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged

and participated in a continuous course of conduct to conceal adverse material information about CSI's reliance upon illegal kickbacks, improper off-label promotions, and other violations of applicable laws and regulations in order to drive sales of its product, as specified herein.

- 378. The Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information, and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of CSI's value, performance, and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and omitting to state material facts necessary in order to make the statements made about CSI's business, specifically that the Company relied upon illegal kickbacks, improper off-label promotions, and other violations of applicable laws and regulations in order to drive sales of its product, in the light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business that operated as a fraud and deceit upon the purchasers of CSI's securities during the Class Period.
- 379. Betterley's primary liability arises from the following facts: (i) Betterley was a high-level executive and/or director of the Company during the Class Period and members of the Company's management team or had control thereof; (ii) Betterley, by virtue of his responsibilities and activities as a senior officer of the Company was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports, particularly with respect to the illegal

kickbacks, improper off-label promotions, and other violations of applicable laws and regulations that the Company relied upon in order to drive sales of its product; (iii)

Betterley enjoyed significant personal contact and familiarity with Martin and was advised of and had access to other members of the Company's management team, internal reports and other data and information about the Company's finances, operations, and sales at all relevant times; (iv) Betterley was aware of the Company's dissemination of information to the investing public which he knew or recklessly disregarded was materially false and misleading, or failed to disclose material information that made those statements false and misleading; and (v) Betterley signed certifications pursuant to the Sarbarnes-Oxley Act of 2002 in CSI's annual and quarterly reports filed throughout the Class Period, which contained false and misleading statements of material fact.

- 380. In addition to the duties of full disclosure imposed on Martin and Betterley as a result of making affirmative statements and reports, or participation in the making of affirmative statements and reports to the investing public, they had a duty to promptly disseminate truthful information that would be material to investors, including truthful, complete and accurate information with respect to the Company's operations and performance so that the market prices of the securities would be based on truthful, complete and accurate information.
- 381. The Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Defendants' material misrepresentations and/or omissions were done

knowingly or recklessly and for the purpose and effect of concealing the true condition of CSI's business, specifically that the Company relied upon illegal kickbacks, improper off-label promotions, and other violations of applicable laws and regulations in order to drive sales of its product, from the investing public and supporting the artificially inflated price of the Company's securities. As demonstrated by Defendants' misstatements throughout the Class Period, if Defendants did not have actual knowledge of the misrepresentations and omissions alleged, they were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

- 382. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market price of CSI's securities was artificially inflated during the Class Period. In ignorance of the fact that market price of CSI's securities was artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trade, and/or on the absence of material adverse information that was known to or recklessly disregarded by Defendants but not disclosed in public statements by Defendants during the Class Period, Lead Plaintiffs and the other members of the Class acquired CSI's securities during the Class Period at artificially high prices and were damaged when the value of their securities declined upon disclosure of the truth about Defendants' false and misleading statements and omissions.
- 383. At the time of said misrepresentations and omissions, Lead Plaintiffs and other members of the Class were ignorant of their falsity, and believed them to be true.

Had Lead Plaintiffs and the other members of the Class and the marketplace known the truth regarding CSI's business, specifically that the Company relied upon illegal kickbacks, improper off-label promotions, and other violations of applicable laws and regulations in order to drive sales of its product, which were not disclosed by Defendants, Lead Plaintiffs and other members of the Class would not have purchased or otherwise acquired their CSI securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

- 384. By virtue of the foregoing, Defendants have violated Section 10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder.
- 385. As a direct and proximate result of Defendants' wrongful conduct, Lead Plaintiffs and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

COUNT II

Violation of Section 20(a) of The Exchange Act Against Betterley

- 386. Lead Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.
- 387. Martin and Betterley acted as controlling persons of CSI within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, and ownership and contractual rights, participation in and/or awareness of the Company's core operations and/or intimate knowledge of the false statements filed by the Company with the SEC and otherwise disseminated to the investing public, Martin

and Betterley had the power to, and did, influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Lead Plaintiffs contend are false and misleading. Martin and Betterley were provided with or had unlimited access to copies of the Company's reports, press releases, public filings, and other statements regarding CSI's business, specifically that the Company relied upon illegal kickbacks, improper off-label promotions, and other violations of applicable laws and regulations in order to drive sales of its product, prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

- 388. Martin and Betterley had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, are presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.
- 389. As set forth above, CSI violated Section 10(b) and Rule 10b-5 by its acts and omissions as alleged in this Complaint. By virtue of his position as a controlling person, Betterley is liable pursuant to Section 20(a) of the Exchange Act as a control person of CSI, the primary violator. As a direct and proximate result of Martin and Betterley's wrongful conduct, Lead Plaintiffs and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

XV. PRAYER FOR RELIEF

WHEREFORE, Lead Plaintiffs prays for relief and judgment, as follows:

- (a) Determining that this action is a proper class action under Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure;
- (b) Awarding compensatory damages in favor of Lead Plaintiffs and the Class against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;
- (c) Awarding Lead Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including attorney's fees and expert fees; and
 - (d) Such other and further relief as the Court may deem just and proper.

XVI. JURY TRIAL DEMANDED

Lead Plaintiffs hereby demand a trial by jury of all issues so triable.

Dated: June 28, 2016 Respectfully submitted,

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